In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 13, 2024

MICHAEL RAY WILLIAMS,	*	PUBLISHED
Petitioner,	*	No. 19-1269V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Influenza ("Flu") Vaccine; Fibromyalgia.
Respondent.	*	

Andrew Donald Downing, Downing, Allison & Jorgenson, Phoenix, AZ, for Petitioner.
Julianna Rose Kober, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On August 26, 2019, Michael Ray Williams ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018),[2] alleging that he suffered from injuries, including fibromyalgia ("FM"), neuropathy, fatigue, polyarthralgia, reactivated Epstein Barr virus ("EBV"), and "unusual reactions to various stimuli including medical procedures, etc." as a result of receiving an influenza ("flu") vaccine on September 4, 2016. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating "this case is not appropriate for

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

compensation under the terms of the Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 19).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards,[3] the undersigned finds Petitioner has failed to provide preponderant evidence that the flu vaccine caused his alleged injury of FM.[4] Thus, Petitioner has failed to satisfy his burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition must be dismissed.

I. ISSUES TO BE DECIDED

There are two factual issues to resolve. The parties dispute Petitioner's diagnosis and the onset of his injury. Joint Prehearing Submission ("Joint Submission"), filed Nov. 3, 2023, at 1 (ECF No. 108). Although Petitioner alleged several injuries in his Petition, in the joint submission the parties narrowed the alleged injury to FM. Id. at 2; see also Petitioner's Prehearing Submission ("Pet. Submission"), filed Oct. 10, 2023, at 1 (ECF No. 97).

The parties also dispute causation, specifically whether Petitioner's alleged FM was caused by his flu vaccination. Joint Submission at 2.

II. BACKGROUND

A. Medical Terminology

Fibromyalgia, or FM, "is a commonly encountered disorder characterized by chronic widespread musculoskeletal pain and related symptoms along with multiple painful tender points." Pet. Ex. BB.2 at 1.[5] The diagnosis of FM is made by using the diagnostic criteria published by the American College of Rheumatology ("ACR") based on "the presence of

[3] While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[4] Petitioner narrowed his injury to FM to reflect his experts' opinions, specifically the opinion of Dr. Jeret, who opined that due to an absence of objective data, he could not confirm that Petitioner had small fiber neuropathy. See Pet. Ex. BB at 11. Since the parties' joint submission and Petitioner's prehearing submission confirm that the alleged injury is FM, the undersigned does not discuss the parties' experts' opinions or medical literature related to small fiber neuropathy or the other injuries alleged in the petition.

[5] Dan Buskila et al., Etiology of Fibromyalgia: The Possible Role of Infection and Vaccination, 8 Autoimmunity Rev. 41 (2008).

widespread pain" of both sides of the body, above and below the waist, and including axial skeletal pain along with points of tenderness. Pet. Ex. DD.6 at 2.[6] "[C]ore symptoms [] include pain, fatigue, and mood and sleep disturbances." Id.

This Decision references three different sets of diagnostic criteria for FM promulgated by the ACR in 1990, 2010, and 2011.

The 1990 criteria required a history of widespread pain and pain in 11 of 18 "tender point sites on digital palpation." Pet. Ex. BB.14 at 12.[7] Pain was considered widespread when it was bilateral (on both sides of the body), above and below the waist, and included "axial skeletal pain." Id. To assess the presence of tender points, the evaluator performed digital palpation using "an approximate force of 4 kg." Id. And the widespread pain "must have been present for at least [three] months." Id. The specific tender point sites included bilateral areas of the occiput (back of the head), cervical spine, trapezius muscles, above the scapula spine, ribs, hips, buttocks, and knees. Id.

The ACR 2010 diagnostic criteria eliminated the examination of tender points, incorporated the presence of widespread pain in 19 different areas,[8] and added key symptoms ("fatigue, waking unrefreshed, cognitive symptoms") along with severity scales to measure symptom severity. Pet. Ex. BB.16 at 8.[9] As with the 1990 criteria, symptoms should be present for three months. Id. But in the 2010 criteria, the widespread pain index ("WPI") was based on the areas which the patient had experienced pain "over the last week." Id.

The 2010 criteria were modified in 2011 to substitute a physician's evaluation of symptom sensitivity for the patient's self-report of symptom intensity. Pet. Ex. BB.17 at 8.[10] The modified criteria are now referred to as the 2011 criteria. See, e.g., Resp. Ex. D at 3. Both the 2010 and 2011 criteria require that the symptoms be present for "at least three months." Pet. Ex. BB.16 at 8; Pet. Ex. BB.17 at 9. And both the 2010 and 2011 criteria relative to the WPI use

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[6] Juan J. García et al., Altered Profile of Chemokines in Fibromyalgia Patients, 51 Annals Clinical Biochemistry 576 (2013).

[7] Frederick Wolfe et al., The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia, 33 Arthritis & Rheumatology 160 (1990).

[8] The areas of pain in both the 2010 and 2011 ACR diagnostic criteria include bilateral pain in the following areas: shoulder girdle, upper arm, lower arm, hip, upper leg, lower leg, jaw, chest, abdomen, upper back, lower back, and neck. Pet. Ex. BB.16 at 8; Pet. Ex. BB.17 at 9.

[9] Frederick Wolfe at el., The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity, 62 Arthritis Care & Res. 600 (2010).

[10] Frederick Wolfe et al., Fibromyalgia Criteria and Severity Scales for Clinical and Epidemiological Studies: A Modification of the ACR Preliminary Diagnostic Criteria for Fibromyalgia, 38 J. Rheumatology 1113 (2011).

an assessment based on the location of pain "over the last week." Pet. Ex. BB.16 at 8; Pet. Ex. BB.17 at 9.

B. Procedural History

Petitioner filed his petition on August 26, 2019. Petition. Along with his petition, Petitioner filed medical records and other supporting documentation. Pet. Exs. A-M. The case was reassigned to the undersigned on October 4, 2019. Order dated Oct. 4, 2019 (ECF No. 6).

On April 30, 2020, Respondent filed his Rule 4(c) report arguing against compensation. Resp. Rept. at 1. Between April 2020 and December 2020, Petitioner filed additional medical records and affidavits. Pet. Exs. N-Q.

On December 15, 2020, the undersigned held an onset hearing. Order dated Jan. 4, 2021 (ECF No. 35). The undersigned could not determine diagnosis or onset based solely on the factual testimony at the hearing. Id. at 2. She directed the parties to obtain expert reports. Id.

On May 5, 2021, Petitioner filed an expert report from Dr. Curt Hagenau. Pet. Ex. R. On July 2 and August 2, 2021, Respondent filed expert reports from Drs. Dara Jamieson and Roland Staud. Resp. Exs. A, C.

The undersigned held a Rule 5 conference on September 14, 2021. Rule 5 Order dated Sept. 14, 2021 (ECF No. 47). She was unable to provide her preliminary findings. Id. at 1. She requested an entitlement hearing if the parties were unable to settle the case. Id. at 1-2. On July 13, 2022, an entitlement hearing was scheduled to begin on December 5, 2023. Prehearing Order dated July 13, 2022 (ECF No. 64).

On December 9, 2022, Petitioner filed additional expert reports from Drs. Joseph Jeret and Omid Akbari. Pet. Exs. BB, DD. Respondent filed supplemental reports from Drs. Jamieson and Staud on March 27, 2023. Resp. Exs. D-E. On June 7, 2023, Petitioner filed responsive reports from Drs. Jeret and Akbari. Pet. Exs. FF, GG. Between January 2022 and October 2023, Petitioner continued to file updated medical records, affidavits, and other exhibits. Pet. Exs. S-Y, AA, HH, II, JJ, KK, LL, MM, NN, OO, PP. QQ, RR, 1-7.

On November 17, 2023, Respondent requested the December 2023 entitlement hearing be continued to early spring of 2024. Motion for Continuance, filed Nov. 17, 2023 (ECF No. 112). On November 21, 2023, a status conference was held where the December 2023 entitlement hearing was cancelled and the parties were offered a new hearing date in June 2024. Order dated Nov. 21, 2023 (ECF No. 114). The parties subsequently chose to submit the case for a ruling on the record in lieu of rescheduling the entitlement hearing. Joint Status Rept., filed Nov. 29, 2023 (ECF No. 116). The record for the case was then closed. Order dated Nov. 29, 2023 (ECF No. 117).

This matter is now ripe for adjudication.

C. Factual History

1. Summary of Medical Records[11]

a. Pre-vaccination and Vaccination Records

Prior to vaccination, Petitioner had a significant medical history including diagnoses of hypertension, obstructive sleep apnea, hypercholesterolemia, Vitamin D deficiency, benign prostatic hypertrophy, allergic rhinitis, edema, abnormality of the red blood cells, weight gain, and right upper quadrant pain. Pet. Ex. C at 42. At a visit with his primary care physician, Dr. John Thomas, on April 29, 2014, Petitioner complained of swelling in his lower extremities, shortness of breath when bending over, rash, bruising easily, abdominal pain, and right upper quadrant tenderness. Id. at 39-40. Petitioner also had multilevel degenerative disc disease as evidenced by an magnetic resonance imaging ("MRI") of the lumbar spine performed on May 21, 2014, that showed multilevel degenerative disc disease from L5 to S1. Id. at 54-55.

In November 2014, Petitioner had thrombophlebitis of the lower extremity (right calf) and acute sinusitis. Pet. Ex. C at 32. In May 2016, Petitioner had a borderline elevated hemoglobin A1C (5.7, normal range < 5.7 %), and records noted his prescription for Metformin[12] was refilled. Id. at 22.

Petitioner also had infectious illnesses and allergies. See generally Pet. Ex. B. Records from The Little Clinic show Petitioner was treated for otitis media (ear infection), allergic rhinitis, sore throat, cough, congestion, and acute upper respiratory infection in 2014, 2015, and 2016. See generally id.

In addition to the above history, Petitioner was evaluated by Dr. Williams David Tissot for kidney stones in 2015 and 2016. See Pet. Ex. MM. at 4. On July 15, 2015, he had kidney stones in his left kidney, with the largest being 4 mm. Id. at 29. Petitioner also had "microscopic hematuria,[13] [right] flank pain [] and back pain." Id. On July 20, 2016, he returned to see Dr. Tissot for benign prostatic hyperplasia and kidney stones. Id. at 26. Abdominal X-rays showed possible left distal ureteral calculus. Id. at 40.

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[11] The undersigned has reviewed all of Petitioner's medical records but for the sake of brevity only summarizes those most relevant to the issues herein. For example, records related to dental care, and Dr. Mowery's records related to a nosebleed, sinusitis, rosacea, and facial pain have not been summarized. Further, not all of Petitioner's visits to his physicians are summarized.

[12] Metformin hydrochloride is "a biguanide antihyperglycemic agent that potentiates the action of insulin, used in the treatment of type 2 diabetes mellitus." Metformin Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30875 (last visited Sept. 26, 2024).

[13] Hematuria, also known as erythrocyturia, is "blood (erythrocytes) in the urine." Hematuria, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=21814 (last visited Sept. 26, 2024).

Petitioner received the flu vaccination at issue on September 4, 2016.[14] Pet. Ex. A at 1-4.

b. Post-vaccination Records

Over two months post-vaccination, on November 18, 2016, Petitioner saw Dr. Tissot for complaints of a kidney stone with hematuria. Pet. Ex. MM at 23. In the review of systems, Petitioner denied fever, tiredness, back pain, neck pain, numbness, or tiredness. Id. at 24. Dr. Tissot documented Petitioner had experienced gross hematuria ("GH") and "right flank pain" but that these symptoms had resolved. Id. at 25. If Petitioner continued to have pain or hematuria, Dr. Tissot planned to order a computed tomography ("CT") scan. Id. Dr. Tissot did not document any back pain or back stiffness. Id. at 23-25.

Approximately one month later, on December 21, 2016, Petitioner presented to Nurse Practitioner Salimah Jones at The Little Clinic with complaints of sinus pressure since December 7, 2016. Pet. Ex. B at 6. He reported congestion with associated ear pain for the past two weeks, with a severity of 6 out of 10, discolored postnasal drainage, cough, dental pain, diffuse facial pain, and headache. Id. He also complained of wheezing and shortness of breath. Id. Petitioner's prior receipt of the seasonal flu vaccine was documented, and no adverse effects were noted. Id. Petitioner was diagnosed with an acute upper respiratory infection, and prescriptions for Medrol Dosepak, Zithromax ("Z-Pak"), and Promethazine dextromethorphan syrup were given. Id. at 7.

Moving forward to 2017, Petitioner returned to The Little Clinic on April 18, 2017 and saw family Nurse Practitioner Tiffany Johnson, with complaints of seasonal allergies for 10 days. Pet. Ex. B at 4. Review of systems was positive for watery, itchy, red eyes and runny nose. Id. Examination showed red eyes with clear drainage. Id. Diagnosis was seasonal allergic conjunctivitis and rhinitis. Id. at 5. Eye drops were given. Id. Petitioner did not report having pain, and his pain scale was documented as 0/10. Id. at 4.

On June 13, 2017, Petitioner saw Dr. Thompson for a physical examination with fasting laboratory studies. Pet. Ex. C at 12. Under the category about "Other Concerns," Petitioner reported that his insurance did not cover lab studies for testosterone or *Helicobacter pylori*. Id. There is no documented complaint of pain. See id. Review of symptoms did not include any problems with pain. Id. at 14. Petitioner's general appearance was "[n]ormal . . . in no acute distress." Id. Physical examination revealed normal skin, normal chest with "no costochondral tenderness," back and spine were "normal" with "no costovertebral angle tenderness," and spine was "nontender to palpation." Id. Musculoskeletal examination was normal. Id. Neurological

[14] Petitioner's Vaccine Administration and Consent record notes two different dates, September 3, 2016, and September 4, 2016. Pet. Ex. A at 4. However, the billing record states the order for vaccination was filled on September 4, 2016. Id. at 6. Also, the Vaccine Adverse Event Reporting System ("VAERS") report filed in 2019 states that the vaccination was administered on September 4, 2016. Id. at 14. The parties have not raised an issue with the date of September 4, 2016, as the accurate date of vaccination. See, e.g., Joint Submission. Therefore, the undersigned finds September 4, 2016, is the day that Petitioner received his flu vaccination.

examination was normal and nonfocal, and Petitioner's "sensory exam[ination] [was] intact to touch." Id. at 14-15.

Petitioner sought chiropractic treatment on June 24, 2017, and at that visit he complained of pain in his hips and neck while walking and bending. Pet. Ex. J at 1. He complained of low back pain and "neck pain." Id. at 5. Petitioner completed a questionnaire that stated, "Sept. 2016 Back stiffness." Id. at 1. Petitioner also reported numbness and tingling, stating "arms get numb/tingly." Id. Laying on the left side relived the pain, and massage temporarily helped the pain. Id. Petitioner returned for chiropractic treatment on June 26. Id. at 5. He reported low back pain with pain 2-3/10. Id. He also complained of arm numbness that was better after adjustment. Id. On June 30, he again complained of low back pain, and his pain was 2/10. Id. Arm numbness and tingling was improved. Id. On July 6, Petitioner reported low back pain and neck with arm numbness. Id.

On July 20, 2017, Petitioner sought treatment from Dr. Tissot for hematuria and complaints of a kidney stone. Pet. Ex. MM at 20. He denied chills, nausea, or back pain. Id. at 20-21. Problem list included "right flank pain." Id. A kidney, ureter, and bladder ("KUB") X-ray showed "[n]o definite radiopaque renal calculi" but "[c]alcified phlebolith versus small distal LEFT ureteral stone." Id. at 39. The study also showed "[l]ower lumbar facet sclerosis"[15] with "bony bridging at the lumbosacral junction." Id. Dr. Tissot noted that Petitioner had kidney stones, stating "the current stone is in the left kidney (several (largest 4 mm))." Id. at 20.

That same date, July 20, 2017, Petitioner saw Dr. Thompson complaining of "back trouble." Pet. Ex. C at 8. At this visit, he reported "having body aches since September 12, 2016." Id. Onset was described as sudden. Id. Petitioner stated that one week after receiving his flu shot, "his entire back seized up." Id. The pain was "sharp/stabby," and the pain was better "laying flat on his back." Id. Pain score was 5-6/10. Id. Petitioner complained of "pain all over his body" and numbness in his hands and feet. Id. He expressed concern about his inability to exercise, stating that he previously worked out three times per week, but "now struggles working out [one] day [per week], and it takes him an entire day to recover." Id. Physical examination was normal, with full range of motion. Id. at 10. Neurological examination was also normal, with normal upper and lower extremity strength, and "sensory exam[ination] [was] intact to touch." Id. Laboratory studies were normal, including normal erythrocyte sedimentation rate ("ESR"),[16] normal rheumatoid factor ("RF"),[17] C-reactive protein

[15] Sclerosis is "an induration or hardening, such as hardening of a part from inflammation, increased formation of connective tissue, or disease of the interstitial substance." Sclerosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=45030 (last visited Oct. 29, 2024).

[16] Erythrocyte sedimentation rate is "the rate at which erythrocytes precipitate out from a well-mixed specimen of venous blood . . . . [ESR] is increased . . . due to inflammatory disease, hyperfibrinogenemia, active inflammatory disease, and anemia." Erythrocyte Sedimentation Rate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=102146 (last visited Oct. 24, 2024).

("CRP"),[18] and antinuclear antibody ("ANA").[19] Id. at 10-11. Folic acid levels were slightly low at 5.1 (with normal > 5.4 ng/mL). Id. at 10. Dr. Thompson assessed Petitioner with FM, polyarthralgia, fatigue, obstructive sleep apnea, and hypotestosterone. Id.

Petitioner returned to see Dr. Thompson for follow-up on July 28, 2017, and on this date his pain was 8/10. Pet. Ex. C at 2. Under musculoskeletal examination, Dr. Thompson noted that Petitioner had "symmetric trigger points over classic [FM] sites." Id. at 4.

Dr. Susan O. Harwell, rheumatologist, saw Petitioner on August 10, 2017, at the request of Dr. Thompson for "polyarthralgia." Pet. Ex. D at 5. Dr. Harwell noted that Petitioner had "a largely unremarkable work-up" with normal creatine phosphokinase ("CPK"),[20] ESR, CRP, RF, thyroid-stimulating hormone ("TSH"),[21] Vitamin D,[22] and negative ANA. Id. Petitioner reported that in September, he had "abrupt onset severe back pain from cervical to sacrum down spine and lateral spinal muscles." Id. About seven months later, "his pain spread to include

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[17] Rheumatoid factors are "antibodies. . . are found in the serum of about 80 percent of persons with classical or definite rheumatoid arthritis. . . . Rheumatoid factors also occur in other connective tissue diseases and some infectious diseases." Rheumatoid Factor, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=74591(last visited Oct. 24, 2024).

[18] C-reactive protein "is an acute-phase reactant protein used to indicate to indicate an inflammatory disease." C-Reactive Protein, Mosby's Manual of Diagnostic and Laboratory Tests 165 (6th ed. 2018).

[19] Antinuclear antibodies are "antibodies directed against nuclear antigens . . . frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjögren syndrome, and mixed connective tissue disease . . . ." Antinuclear Antibodies, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=56804 (last visited Oct. 24, 2024).

[20] Creatine phosphokinase is "an Mg^{2+}-activated enzyme of the transferase class that catalyzes the phosphorylation of creatine by [adenosine triphosphate ("ATP")] to form phosphocreatine. . . . Differential determination of isoenzymes is useful for clinical diagnoses." Creatine Kinase, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=11582 (last visited Oct. 24, 2024).

[21] Thyroid-stimulating hormone, also known as thyrotropin, is "a glycoprotein anterior pituitary hormone [] that promotes the growth of, sustains, and stimulates hormonal secretion of the thyroid gland." Thyrotropin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50030 (last visited Oct. 24, 2024).

[22] Vitamin D is one of "two fat-soluble compounds with antirachitic activity. . . . Deficiency of vitamin D can result in rickets in children and osteomalacia in adults, while ingestion of excess levels can lead to hypercalcemia, mobilization of calcium from bone, and renal dysfunction." Vitamin D, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=118584 (last visited Oct. 24, 2024).

bilateral thighs and arms." Id. Petitioner reported a "progressive weakness, mostly proximal [lower extremity] muscles and entire arms and shoulders." Id. He stated he was unable to exercise or lift weights, although he was able to conduct his activities of daily living. Id. He had also developed numbness in the hands and feet, and over the "past few months" had leg cramps that interfered with sleep. Id. Dr. Harwell wrote that Petitioner "[f]e[lt] profound fatigue and [] decreased endurance," as well as myalgias, and that "[t]he pain [was] everywhere." Id.

At the August 17, 2017 visit with Dr. Harwell, Petitioner's physical examination was normal except for pitting edema of the lower extremities. Pet. Ex. D at 6. Neurological examination revealed normal strength in all muscles with 4/5 strength in distal intrinsic hand muscles and proximal upper motor strength. Id. Range of motion was limited in the left ankle, but otherwise normal. Id. Coordination was normal. Id. Petitioner had no tenderness of the spinous process or paraspinal muscles. Id. Upper extremity and lower extremity examination was normal with normal range of motion of wrists, elbows, shoulders, hips, knees, and feet. Id. at 7. Petitioner had reduced range of motion with plantar flexion and extension of his left ankle. Id. Dr. Harwell's assessment was "muscle weakness." Id. She noted "sudden onset of progressive weakness in addition to peripheral neuropathy" with "reduced patellar reflexes." Id. She questioned whether Petitioner may have a neurological problem and recommended referral to Dr. Curtis Hagenau, a neurologist. Id.

MRI of the brain was performed on September 26, 2017, and was unremarkable. Pet. Ex. C at 48. Electromyography ("EMG")/ nerve conduction study ("NCS")[23] was done on October 6, 2017, and was "essentially normal . . . of both upper limbs." Id. at 58. The study showed decreased median sensory nerve amplitude, but this finding was interpreted as "technical in nature." Id. There was "no [] evidence of nerve entrapment or generalized peripheral neuropathy." Id.

Petitioner returned to see Dr. Harwell on October 20, 2017. Pet. Ex. D at 2. At this visit, Petitioner reported he was about the same. Id. He had seen a neurologist and had a normal EMG. Id. Dr. Harwell noted that Petitioner "fe[lt] strongly that the flu shot was to blame." Id. He was "stiff all over" and unable to exercise. Id. Dr. Harwell opined that Petitioner's work-up for connective tissue disorder ("CTD") was negative and did not explain Petitioner's muscle weakness. Id. at 4. When asked about FM, Dr. Harwell explained that "[w]hile [FM] can cause fatigue and subjective muscle weakness, it would not be responsible for actual muscle weakness and reduced reflexes and should be thought of as a diagnosis of exclusion." Id. She discussed referring Petitioner to a tertiary referral center. Id.

[23] Electromyography is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." Electromyography, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854 (last visited Oct. 24, 2024). Nerve conduction studies are "the measurement of the conduction velocity and latency of peripheral nerves." Nerve Conduction Studies, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=109043 (last visited Oct. 24, 2024).

On November 13, 2017, Petitioner saw neurologist Dr. Gretchen Campbell. Pet. Ex. E at 1-6. Chief complaints were "muscle weakness, pain[,] and fatigue." Id. at 1. Petitioner repeated his history of a flu shot in September 2016, followed the next week by "stiffness, spasm." Id. He stated that the spasms had progressed from his paraspinal muscles and his lower back, and the spasms were now in his hips, thighs, across his shoulders, and down to his arms and hands. Id. He also complained of "[l]ightning bolt pain" in his fingers and toes, exercise intolerance, and constant fatigue. Id. Dr. Campbell documented that labs were essentially normal, brain MRI was normal, cervical MRI showed minor disc bulges but a normal spinal cord, and EMG of the upper extremities was "essentially normal." Id. at 1-2. Petitioner was not employed and was seeking social security disability. Id. at 2. Physical examination was normal except for 4/5 strength of the bilateral upper extremities, 4+/5 of bilateral hip flexors, mild tremor of the right upper extremity, and decreased reflexes 1/4 in the "biceps, triceps, brachioradialis, patellar, and ankle jerks." Id. at 3. Dr. Campbell's impression was numbness of the hands and feet, muscle weakness of the proximal arms and legs. Id. at 5. Dr. Campbell recommended checking Petitioner's B12 level and testing for a Methylenetetrahydrofolate reductase ("MTHFR") genetic mutation.[24] Id. If these tests were normal, Dr. Campbell planned to refer Petitioner back to his rheumatologist and primary care provider for future care. Id. The tests were performed, and while the MTHFR DNA analysis showed two mutations, C677T and A1298C, these variants were described as unlikely to be clinically significant based on published reports. Id. at 10.

Petitioner next saw Nurse Practitioner Anna Guessetto on January 4, 2018, for a "[f]lu shot reaction." Pet. Ex. F at 44. Petitioner reported that "shortly after" receiving the flu shot in September 2016, he was diagnosed with the flu and had "back stiffness, hand swelling, limb numbness, and extreme fatigue." Id. Ms. Guessetto discussed "that the flu shot either caused an immune reaction or [] an underlying immune reaction." Id. In consultation with Dr. Daniel Kalb, extensive lab work was ordered. Id. at 44-46.

Petitioner returned to see Dr. Kalb on February 6, 2018, and Dr. Kalb assessed Petitioner with MTHFR deficiency[25] and FM. Pet. Ex. F at 38-42. Dr. Kalb wrote "[m]y assumption is that the flu shot in 2016 affected his immune system and may have resulted in a reactivation of EBV."[26] Id. at 42. Dr. Kalb further postulated that the chronic EBV "may have led to the

[24] MTHFR is "a key enzyme in the folate pathway and is responsible for the metabolism of homocysteine." See Pet. Ex. E at 10.

[25] MTHFR deficiency is "a common, autosomal recessive, inborn error of folate metabolism caused by mutation in the MTHFR gene . . . . Clinical manifestations, age of onset, and severity are highly variable; characteristics include signs of neurologic damage ranging from psychiatric symptoms to fatal developmental delay, microcephaly, ectopia lentis, and thrombosis." Methylenetetrahydrofolate Reductase (MTHFR) Deficiency, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30976 (last visited Oct. 14, 2024).

[26] EBV testing showed elevated EBV Nuclear Antigen IgG, VCA Antibodies IgG, and Early Antigen IgG, indicative of "previous infection and early antigen antibody remains positive." Pet. Ex. F at 35; 29. EBV testing repeated on July 14, 2018 showed "early antigen antibody remains positive." Id. at 29.

development of his neuropathy and [FM] symptoms." Id. Dr. Kalb recommended a diet to reverse autoimmune diseases, The Plant Paradox diet (developed by Dr. Steven Gundry); an anti-viral medication; an anti-fungal medication; low-dose naltrexone[27] as a supplement that "boosts the immune system and treats any autoimmune disease;" as well as additional probiotic, prebiotic, and enzyme supplements. Id. at 42.

On January 7, 2018, Petitioner presented to The Little Clinic with flu-like symptoms that began the prior day. Pet. Ex. B at 1. He had fatigue and body aches "all over," including his hips and legs. Id. Testing for flu A was positive. Id. at 2. Petitioner was also diagnosed with bronchitis. Id.

Dr. Kalb saw Petitioner for follow-up in April, May, July, and November 2018. Pet. Ex. F at 3-37. Testing was done for heavy metals, urine mycotoxins, food sensitivities, and allergies, and medications and supplements were prescribed and adjusted. Id. at 2-3. Dr. Kalb wrote that EBV testing done November 19, 2018 showed "previous infection, early antigen antibody is lower but remains positive." Id. at 7. Quantitative polymerase chain reaction ("PCR") testing for EBV was negative. Id. at 8. Petitioner's last visit with Dr. Kalb was March 8, 2019. Id. at 1. Dr. Kalb's notes from that visit state, "I am theorizing that the mild elevation in temperature associated with activity, along with the flu-like symptoms that are relieved by rest, are due to an abnormal immune reaction and not due to infection." Id. The plan was to test for "heavy metals and Mycotoxins" and start a "ketogenic diet." Id. Dr. Kalb diagnosed FM, MTHFR deficiency, obstructive sleep apnea, and hypertension. Id.

On May 12, 2019, Petitioner saw a new physician, Dr. Phaythoune Chothmounethinh, with concerns about "daily fevers for about a year of 99 to 99.6, and . . . up to 101 [degrees]," accompanied by extreme fatigue and his history of FM, which he attributed to his 2016 flu shot. Pet. Ex. G at 1. His left hand had swelling and numbness. Id. Dr. Chothmounethinh's assessment was fatigue. Id. Other problems included EBV, MTHFR deficiency, obstructive sleep apnea syndrome, and hypertension. Id. at 2. Petitioner returned for follow-up on July 23, 2019, complaining of dyspnea on exertion and having an adverse reaction to CT contrast dye. Id. at 5.

Next, Petitioner saw Dr. Daniel N. Sacks on June 5, 2019, at the request of Dr. Chothmounethinh, for complaints of nasal and sinus problems. Pet. Ex. H at 1. Petitioner complained of years of chronic sinus symptoms, right submandibular gland swelling, and fevers. Id. He also reported that a previous flu vaccine "resulted in an EBV infection." Id. Dr. Sacks recommended allergy testing and further evaluation with a CT scan and nasal endoscopy if allergy testing failed to identify the etiology of Petitioner's complaints. Id. at 3. Petitioner returned two weeks later for follow-up. Id. at 9. Allergy testing was "relatively unremarkable."

[27] Naltrexone "is an opioid antagonist; administered . . . in the treatment of opioid or alcohol abuse." Naltrexone Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=33113 (last visited Oct. 14, 2024). Low-dose naltrexone "refers to daily doses of naltrexone that are approximately 1/10th of the typical opioid addiction treatment dosage." Jarred Younger et al., The Use of Low-Dose Naltrexone (LDN) as a Novel Anti-Inflammatory Treatment for Chronic Pain, 33 Clinical Rheumatology 451, 451-52 (2015).

Id. Petitioner reported improvement in symptoms since taking an antibiotic for a dental infection. Id. Dr. Sacks recommended a trial of ipratropium[28] with further evaluation dependent upon his response to treatment. Id. at 10.

Petitioner returned to see Dr. Tissot on July 10, 2019, complaining of the onset of hematuria one week ago. Pet. Ex. MM at 14. Petitioner reported "gross hematuria, gross hematuria with clots, flank pain (right)[,] and back pain." Id. CT was performed on July 10 and was normal. Id. at 15, 38.

A stress echocardiogram, with treadmill exercise testing, was performed October 2, 2019 and was negative for cardiac ischemia. Pet. Ex. LL at 4. Exercise time was 5.5 minutes, and Petitioner tolerated the procedure well. Id. X-rays of Petitioner's hips were performed on October 4, 2019, and showed mild to moderate osteoarthritic changes of the left and right hip with "joint space narrowing and osteophytic spurring." Id. at 3.

On March 10, 2020, Petitioner sought care from rheumatologist Dr. James E. Gore at Vanderbilt Medical Center Adult Hospital for "chronic joint and muscle pain." Pet. Ex. N at 32. After obtaining extensive laboratory studies and spinal X-rays, Petitioner returned to see Dr. Gore on March 18, 2020. Id. at 3. Physical examination of muscles was normal with "no proximal weakness; no distal weakness; [and] no atrophy." Id. at 6. Petitioner had no abnormal deep tendon reflexes or motor neuropathy, but he did have bilateral lower extremity neuropathy. Id. Dr. Gore's assessment was "chronic neuropathic symptoms of his hands and feet" with normal folate level. Id. at 7. Regarding Petitioner's neuropathy and fatigue, Dr. Gore noted that his B6 and B12 vitamin levels were low, and recommended Petitioner supplement with a B complex. Id. at 7-8. Dr. Gore assessed Petitioner with "[c]hronic midline low back pain without sciatica," noting his history of "low back pain and stiffness," and commented that his X-rays showed "mild multilevel degenerative changes on lumbar spine." Id. at 8-9. He recommended physical therapy for Petitioner's low back. Id. at 8. Laboratory studies for inflammatory markers were ordered for Petitioner's left-hand pain; however, it does not appear that Petitioner returned for follow-up. Id.

On August 24, 2020, Petitioner returned to see Dr. Thompson to reestablish care. Pet. Ex. O at 3. He reported that he exercised twice per week. Id. Neurological examination was normal with "[n]ormal strength and tone, [n]ormal sensation." Id. at 4. Musculoskeletal examination was also normal. Id. at 5. Dr. Thompson's assessment was hypertension, hypotestosteronemia, enlarged prostate, obstructive sleep apnea, polyarthralgia, degenerative disc disease, anterior cervical lymphadenopathy, tinnitus, neurological dysfunction, fatigue, night sweaters, chronic fever, and post-nasal drainage. Id.

[28] Ipratropium bromide is "a synthetic congener of atropine with anticholinergic and antimuscarinic effects . . . [used] in the maintenance treatment of chronic bronchitis, pulmonary emphysema, and other forms of chronic obstructive pulmonary disease, and [ ] for the relief of rhinorrhea associated with rhinitis or the common cold." Ipratropium Bromide, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=26071 (last visited Nov. 13, 2024).

On September 14, 2020, Petitioner sent a message to Dr. Gore through the electronic health records and asked if he could "take or retake a test for chronic inflammatory demyelinating polyneuropathy [("CIDP")]? I [feel] I have some [of] these symptoms and would like to see if I have some form of this." Pet. Ex. U at 58. Dr. Gore responded, "That would need to be done by a neurologist, preferably who you saw before." Id. Petitioner responded that he would ask Dr. Thompson. Id.

Petitioner returned to Dr. Thompson for his annual examination on October 19, 2020. Pet. Ex. O at 20. Petitioner reported that he was "sleeping well," and that he was exercising three to four times per week, except for the past month, due to a sinus infection. Id. The visit's problem list included his history of neurological dysfunction with pain and weakness of the shoulder, arms and legs, and numbness of the hands and feet and noted "[o]nset of symptoms occurred one week after receiving a[] [flu] vaccine." Id. Dr. Thompson prescribed Wellbutrin[29] and to follow up in one month, or as needed. Id. at 23. The records do not reflect that Petitioner requested testing for CIDP.

Petitioner and his wife, Lee Anne Williams, sent a message via the electronic health record to Dr. Gore on January 30, 2021 stating, "We asked why [Petitioner's] symptoms are not [FM]. You gave us an answer[,] but we can't remember what you said could you please tell us again." Pet. Ex. U at 41. Dr. Gore replied two days later, stating, "We discussed Periodic Fever Syndromes." Id.

In August 2021, Petitioner had a follow up visit with Dr. Gore. Pet. Ex. U at 9. Dr. Gore stated that Petitioner had "an unusual presentation [of periodic fever syndrome] since his symptoms began after a flu shot." Id. at 10. Dr. Gore noted that Petitioner had "negative serologies and only a slightly elevated CRP." Id. History of present illness included that he was seen by Dr. Kalb, who thought Petitioner had a viral infection, and prescribed anti-virals, which helped Petitioner's movement and overall pain and stiffness. Id. at 11. Petitioner was currently complaining of episodes of fever with swelling of the right neck lymph nodes associated with severe fatigue. Id. Petitioner reported that his previous numbness in his hands and feet had improved with Vitamin B supplementation. Id. Petitioner tried taking colchicine for his right neck swelling, but it caused excessive sleepiness. Id. at 10. Dr. Gore's assessment was "periodic fever syndrome" and "chronic pain of right knee." Id. at 9. He considered low dose Imuran[30] as treatment for the periodic fever syndrome. Id. at 13.

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[29] Wellbutrin, known generically as bupropion hydrochloride, is "a monocyclic compound structurally similar to amphetamine, used as an antidepressant . . . ." Bupropion Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=7289 (last visited Nov. 13, 2024).

[30] Imuran, known generically as azathioprine, is "the imidazolyl derivative of 6-mercaptopurine, its active metabolite. It is [used] as an immunosuppressive agent for prevention of transplant rejection []; as a disease-modifying antirheumatic drug for treatment of severe, progressive rheumatoid arthritis unresponsive to other agents; and in treatment of a number of autoimmune disorders." Azathioprine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=7289 (last visited Nov. 13, 2024).

Petitioner had pneumonia due to Covid infection in December 2021 through February 2022. Pet. Ex. OO at 3. He was hospitalized due to Covid in January 2022. Id. at 45-47. On March 28, 2022, he was diagnosed with post-Covid syndrome. Id. at 39. His symptoms included alopecia,[31] and "[r]eceptive[32] and [e]xpressive [a]phasia."[33] Id.

On June 6, 2022, Dr. Thompson's records stated that he was referring Petitioner back to neurology "specifically for skin biopsy to check for small fiber sensory neuropathy." Pet. Ex. OO at 4, 34. However, no records documenting a skin biopsy have been filed.

History taken by Dr. Thompson on November 1, 2022 noted that Petitioner felt well with "minor complaints," had decreased energy, but was sleeping well. Pet. Ex. OO at 21. He had stopped using his continuous positive airway pressure ("CPAP") machine for sleep apnea due to claustrophobia. Id. Physical examination was normal, Petitioner had "full range of motion" and "[n]o adenopathy." Id. at 23. Neurological and musculoskeletal examinations were also normal. Id.

Records from Petitioner's virtual visit to Dr. Thompson from April 4, 2023 show that his diagnoses on that day included hypertension, microalbuminuria, elevated liver enzymes, chronic prostatitis, erythrocytosis, periodic fever syndrome, and polymyositis. Pet. Ex. OO at 4. Dr. Thompson wrote, "[t]he patient feels well with minor complaints." Id. It was noted that he continued to follow up with rheumatology. Id. at 7. Petitioner returned to see Dr. Thompson on June 13, 2023, for acute right flank pain, "[c]rampy in nature. Suggestive of kidney stone." Pet. Ex. QQ at 4. At that visit, it was documented that Petitioner continued to take Naltrexone 3 mg per day for FM. Id.

Although additional records from various providers have been filed, they do not materially relate to the issues in dispute here, and so they are not summarized.

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[31] Alopecia is a "lack or loss of hair from skin areas where it normally is present." Alopecia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=1905 (last visited Sept. 27, 2024).

[32] Receptive aphasia is an "inability to understand written, spoken, or tactile speech symbols, due to disease of the auditory and visual word centers." Receptive Aphasia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=57205 (last visited Sept. 27, 2024).

[33] Expressive aphasia, also called motor aphasia, is an "aphasia in which there is impairment of the ability to speak and write . . . . The patient understands many written and spoken words but has difficulty uttering the words." Motor Aphasia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=57201 (last visited Sept. 27, 2024).

2. 2019 VAERS Report

Petitioner filed two VAERS reports. The first one was filed May 2, 2019, and the form was completed by Heather Graves, a healthcare staff person. Pet. Ex. A at 15. However, the patient name on the report was erroneously listed as Lee Anne, Petitioner's wife's name. Id.

A second VAERS report was submitted by Petitioner on May 15, 2019. Pet. Ex. A at 17-18. The date of vaccination was identified as September 4, 2016, and the date of onset of the adverse event was documented as September 14, 2016. Id. at 17. Petitioner described that less than a week after receiving the vaccination, he "started having tight sore muscles and hot inflation along [the] spine in his back." Id. at 18. This caused Petitioner to have aches and pains in his back and "between his ribs." Id. Additionally, he reported neurological problems, including tremor, swelling of the left hand, and numbness, coldness, and weakness in his hands. Id. Petitioner also reported that he had EBV and FM. Id.

3. Petitioner's Affidavits

Petitioner filed several affidavits executed on August 15, 2019. Pet. Ex. 1 at 2-6. Two of these address visits to The Little Clinic. See id. at 2, 5. In one affidavit, Petitioner averred that he saw Ms. Jones, Physician Assistant,[34] on December 7, 2016, at The Little Clinic, and he reported that since receiving the flu vaccine on September 4, he had back stiffness and inflammation "that progressed to whole body aches and fatigue." Id. at 2. He also reported a pain level of 6/10, and they discussed the "vaccine and the symptoms." Id. Petitioner assumed that Ms. Jones documented the conversation in his records.[35] Id. He further averred that Ms. Jones did not treat him or recommend that he seek any treatment. Id.

In another affidavit, Petitioner stated he saw Nurse Practitioner, Ms. Johnson, at The Little Clinic on April 18, 2017, for "itchy watery eyes." Pet. Ex. 1 at 5. He averred that he again reported the same problems described above. See id. Again, Petitioner assumed the problem had been noted in his records.[36] Id. Ms. Johnson did not treat him for his "general body ache symptoms," or recommend that he see a physician. Id.

In another affidavit, Petitioner averred that on September 10 or 11, 2016, he and his wife went to the pharmacy where he received his flu vaccine, and told the pharmacist, Joan R. Ratcliff, that "within [three] days of receiving the [flu] vaccine the muscles in [his] back became inflamed and stiff." Pet. Ex. 1 at 3. Ms. Ratcliff responded by stating that "the flu shot would not have caused that." Id.

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[34] While Petitioner described Ms. Jones as a Physician's Assistant in his affidavit, medical records describe Ms. Jones as a Nurse Practitioner. See Pet. Ex. 1 at 2; Pet. Ex. B at 7.

[35] This conversation is not documented in the medical records. See Pet. Ex. B at 6-7.

[36] This conversation is not documented in the medical records. See Pet. Ex. B at 4-5.

Petitioner also filed an affidavit describing a conversation he had with his dentist, Dr. Chad Hutchison, on October 31, 2017. Pet. Ex. 1 at 4. The dentist "had a difficult time getting [Petitioner] numb." Id. at 4. Petitioner told his dentist of the problems he had experienced since receiving the flu vaccination, and Petitioner averred that his dentist "agreed the neurological symptoms [Petitioner] was experiencing elsewhere could be causing the issue with getting [him] numb." Id.

In the next affidavit, executed August 15, 2019, Petitioner recounted having a reaction to contrast given for a CT scan on July 10, 2019. Pet. Ex. 1 at 6. After the contrast injection, Petitioner "felt hot," which he was told "was a normal reaction." Id. Petitioner stated that the "hot feeling last[ed] [five] days which is not normal." Id. Also, when he was leaving the test, "the nerve in [his] middle finger of his right hand started making his finger jump. [And] [t]he other fingers felt like the nerves were firing. That evening the toes in his right foot were burning. The tingling [and] burning lasted for [three] days." Id.

Petitioner executed another affidavit on July 21, 2020. Pet. Ex. 1 at 1. In it, Petitioner described statements made by Dr. Chothmounethinh during office visits. Id. These statements included that Petitioner had "a million in one condition brought on by the flu shot vaccine," that he "could try and find a flu vaccine clinical study" to help "with the problems caused by the flu vaccine," that all test results were negative, and "the results circle back to the cause being the Flu Shot Injection." Id. In June 2020, when asked via the patient portal whether Dr. Chothmounethinh had found a vaccine clinical study, he responded, "I have not come across any yet but will let you know." Id.

4. Petitioner's Testimony

Petitioner testified at the onset hearing to support his contention that his symptoms started in September 2016. Tr. 5-34.

Petitioner received his flu shot with his wife at the Target pharmacy. Tr. 6. He could not recall having ever received the flu vaccine before. Id. Petitioner explained his "wife started feeling pain in her left arm when [they] went to the grocery store right after Target" but he "didn't have any pain until later on." Id. Petitioner's pain began "a few days later after the flu shot." Tr. 7. He woke up with "burning pain in [his] back and achy muscles." Id. Petitioner described his symptoms as beginning around the spine, which "felt like it was on fire." Tr. 15. Then his left arm began getting weaker, and he developed tremors. Id. As of the date of the onset hearing, December 15, 2021, he continued to have "achy back muscles and sharp pains in his back." Id. He also had a "gland in the right side of his throat that swells up" and "firing of [] nerves in [his] toes and [] fingers." Id. Petitioner also testified that he is "very tired all the time" and that after physical labor, he must rest or nap. Id.

Four or five days after receiving the vaccine, Petitioner returned to the pharmacy and spoke to the pharmacist about whether the flu shot caused Petitioner's pain. Tr. 7-8. The pharmacist told Petitioner that "the flu shot wouldn't have done that." Tr. 8. The pharmacist didn't offer to take notes or fill out any paperwork. Id. Petitioner filed a formal report in 2019 after learning about VAERS. Tr. 8, 13. Petitioner explained he then amended the VAERS report

because the first VAERS report had his wife's name and an adverse event date of September 11, 2016, but his adverse event date "was a few days earlier than that." Tr. 11. However, the amended VAERS report pushed the date further back to September 14, 2016. Tr. 12. Petitioner testified that "[he] didn't tell them that. [He] told them it was earlier than that." Id.

Petitioner went to The Little Clinic on December 21, 2016, because he had an "upper respiratory condition starting." Tr. 15. At the appointment he said his pain levels were 6/10 and he "brought up his flu shot because [he] thought that was [] causing [his] pain level." Tr. 16. He told the provider "about the flu shot, all of the problems [he] was having." Id. Petitioner went back to The Little Clinic on April 18, 2017, for seasonal allergies. Tr. 17. At this appointment, Petitioner told the provider about the symptoms he was attributing to the flu vaccine. Tr. 17-18. Petitioner testified that he regularly goes to appointments at The Little Clinic because "[y]ou don't have to get an appointment. You just walk up there and they let you in." Tr. 23. Both his December 2016 and April 2017 visits were walk-up visits. Tr. 25. Petitioner testified that he never did a "walk up" appointment at The Little Clinic for his back pain. Tr. 25-26.

His next appointment was his yearly check-up with Dr. Thompson on June 13, 2017. Tr. 18-19. Petitioner did not tell Dr. Thompson about any vaccine-related symptoms. Tr. 19. Petitioner was concerned that if he told Dr. Thompson about the vaccine symptoms, "[insurance] wouldn't pay for the examination . . . [b]ecause [he] had problems before mentioning something at another doctor, and they wrote it up and [insurance] would not pay for the exam[ination] then." Id.

Petitioner also saw a chiropractor on June 24, 2017, because he was worried about his back. Tr. 20. Petitioner told the chiropractor about "[his] back and all the pain [he] was having. And [the chiropractor] said he had heard that flu shots cause problems and that's why he wouldn't take one." Id.

Petitioner was first formally treated for his vaccine-related symptoms at his next appointment with Dr. Thompson on July 20, 2017. Tr. 21-22. Petitioner explained he didn't seek formal treatment until July 2017 because "[w]ith professionals telling [him] that [his pain] wasn't the flu shot, [he] just thought [he] had [] aches and pains in his back." Tr. 22. He sought formal treatment because his symptoms got worse, and he had to stop doing activities. Id.

5. Lee Ann Williams' Affidavits and Testimony

Ms. Williams is the wife of the Petitioner. Tr. 35. She received a flu vaccination at the same time and place as Petitioner. Tr. 35-36. In the affidavits she executed in 2019 and 2020, she generally testified that the onset of Petitioner's symptoms occurred about three days or so after vaccination. Pet. Ex. 2 at 1-3.

She also submitted an affidavit on August 15, 2019, that described Petitioner's condition before and after vaccination. See Pet. Ex. 2 at 4. Prior to vaccination, Petitioner "did not complain of constant back stiffness, inflamed back muscles, whole body aches, tingling/feelings of firing in hands and feet, [and] tiredness." Id. He was able to work out at the gym three to five times per week and work in the yard. Id. As of August 15, 2019, Petitioner was unable to do

"prolonged physical activity" and if he did "any type of physical activity," he "require[d] daily naps." Id. She added that if he had a "day long activity," he would plan to "rest the next [two to three] days." Id.

Ms. Williams testified at the onset hearing. Tr. 35. Ms. Williams was with Petitioner when he received his flu vaccine. Tr. 36. That same day, after receiving her flu vaccine, Ms. Williams experienced some stiffness and soreness in her arm. Id. She asked Petitioner "if he had any symptoms, and he said no." Id.

Petitioner received the vaccine on a Saturday and sometime the following week "he started feeling inflammation in his back and the sore stiff muscles." Tr. 36. Petitioner told Ms. Williams that "he felt like [his] spine was on fire." Tr. 37. Ms. Williams explained that "later on he started being fatigued" and continued to have back pain. Id. Ms. Williams asked Petitioner if the pain was due to the gym, or working around the house, or in the house, but Petitioner denied those causes. Id. He just "woke up feeling that way that morning." Id.

Ms. Williams and Petitioner returned to the pharmacist, Ms. Ratcliff, the next weekend and told her about Petitioner's symptoms. Tr. 37. The pharmacist told them the vaccine would not have caused Petitioner's symptoms. Id.

Ms. Williams attended an appointment with Petitioner on December 21, 2016. Tr. 38. At the appointment, Petitioner told the provider his pain was 6/10 and "he had been having pain in his back since receiving the flu shot in the beginning of September." Id. Ms. Williams attended Petitioner's next appointment on April 18, 2017. Tr. 39. At that appointment, Petitioner told the provider "that he was having back stiffness and again, that it had been going on since September when he got the flu shot." Tr. 40.

Ms. Williams did not attend Petitioner's next appointment on June 13, 2017, which was his annual physical. Tr. 40. Prior to the visit, Ms. Williams and Petitioner discussed not telling his doctors about his vaccine symptoms to avoid being charged for a "special visit" by their health insurance. Tr. 41. Ms. Williams was concerned about extraneous charges because at her annual workup the nurse had informed her if "we talked about anything else other than the normal annual physical-type thing, that [she] might have to pay for not just the doctor's visit but any lab work that would be run, which can be several hundred dollars." Id. Ms. Williams and Petitioner also thought a normal physical and bloodwork might show Petitioner's "thyroid or something else was out of whack and causing these symptoms." Id.

6. Other Affidavits and/or Testimony

Affidavits and/or testimony were offered by four lay witnesses, as summarized below.

Petitioner's sister, Ms. Susan Williams Kunczwka, offered two affidavits. Pet. Ex. 6. In her first affidavit, executed on August 12, 2019, she described that before the vaccine, Petitioner "always had energy and did many activities including going to the gym." Id. at 2. She explained the activities Petitioner performed during an August 2015 visit, and she explained that Petitioner "was able to do very little" the next time he visited in June 2017. Id. at 2. In the second affidavit

executed on December 4, 2020, Ms. Kunczwka averred that Petitioner called her around September 11 to complain about symptoms he developed from the September 4 flu vaccine. Id. at 1.

Ms. Kunczwka provided additional detail in her testimony at the hearing. Tr. 44-47. Ms. Kunczwka explained that she is in contact with Petitioner "on a regular basis." Tr. 44. In the fall of 2016, she would talk with Petitioner on the phone "at least twice a month" and they "would e-mail [] two, three times a week." Tr. 45. Ms. Kunczwka first became aware of Petitioner's flu vaccine after a phone call "around [Petitioner's] birthday, at the end of September 2016." Id. Ms. Kunczwka explained she recalls the conversation because Petitioner was impressed that he received a $5 gift card after receiving the flu vaccine at Target and was "just more ecstatic than most people are" to receive a flu vaccine. Tr. 45-46. This call was probably "a week or less than two weeks" after Petitioner received the vaccine. Tr. 46. Petitioner was very concerned about possible side effects and was complaining that he was "just achy, miserable, there was a burning in his back." Id. Ms. Kunczwka testified that Petitioner would usually exchange calls or emails with her after appointments. Tr. 47. She was pretty sure she had received emails from Petitioner complaining about his symptoms. Id. Ms. Kunczwka no longer had copies of those emails at the time of the hearing on December 15, 2020. Id.

Petitioner's friend, Mr. Timothy Munsell executed an affidavit on July 15, 2020, and later testified at the onset hearings. Pet. Ex. 4; Tr. 51-56.

In his affidavit, Mr. Munsell averred that Petitioner had a lot of back pain in the fall of 2016 and "[Petitioner] told [him] at that time that he suspected the flu shot he received in September 2016 may have been the cause of the pain." Pet. Ex. 4 at 1.

At the onset hearing, Mr. Munsell testified that Petitioner began complaining of "back aches and headaches and [] a lot of fatigue" in the fall of 2016. Tr. 51. Mr. Munsell, Petitioner, and their wives would often talk after Sunday school classes at their church. Id. During these talks, Petitioner often mentioned "the health problems that he was experiencing and []the frustration of trying to find a doctor with a good diagnosis and [] trying to get some treatment for these problems." Id. Mr. Munsell also explained that there were "a number of Sundays where [Petitioner's wife] was alone because [Petitioner] was not able to make it [to] church that day just because he was feeling so bad." Tr. 56. In the fall of 2017, Petitioner helped Mr. Munsell replace broken stairs. Tr. 55. Petitioner was able to help Mr. Munsell with the project at that time, although Mr. Munsell had some "concerns . . . beforehand." Id.

Mr. Munsell explained he remembered that Petitioner's health issues began in fall of 2016 rather than in "the spring or summer of [20]17" because Mr. Munsell remembered seeing "the lawn and trees" out the windows of the classroom where he spoke with Petitioner and because Mr. Munsell changed jobs in January of 2017. Tr. 52-53.

Petitioner's hairdresser and friend, Ms. Krista Stevens, executed an affidavit on June 29, 2020. Pet. Ex. 3. Ms. Stevens averred Petitioner was "always full of life," but in "September 2016 everything changed." Id. Ms. Stevens explained that Petitioner complained after getting the flu shot and he became "always tired, achy, and just never felt good." Id.

Mr. Robert Williams, Petitioner's neighbor, executed an affidavit on July 8, 2020. Pet. Ex. 5. He stated that he has known Petitioner since 2014 and that "sometime in late 2016 [Petitioner] told [him] he had become ill after having the flu shot." Id. Mr. Robert Williams noted that Petitioner had discussed his "discomfort that occurred after that flu shot . . . in many conversations." Id.

7. Affidavits of Dr. John R. Thompson

Dr. Thompson submitted two affidavits. The first one was executed on October 19, 2019, at the request of Petitioner. Pet. Ex. 7. In it, Dr. Thompson stated Petitioner "developed sudden onset of back pain extending from his cervical spine to his sacrum within days of receiving a seasonal [flu] vaccine on September 4, 2016." Id. The "pain progressed over the ensuing months to include his shoulders, arms, and thighs, bilaterally," and was "associated with progressive weakness of his proximal muscles . . . and progressive fatigue." Id. Dr. Thompson referred Petitioner to a rheumatologist and a neurologist, who both conducted extensive evaluations that "failed to reveal an etiology for [Petitioner's] symptoms." Id. Dr. Thompson opined that Petitioner's "chronic symptoms represent an adverse reaction directly related to the [flu] vaccine he received on [September 4, 2016]." Id.

The second affidavit from Dr. Thompson was executed on August 3, 2020. Pet. Ex. O at 1-2. Dr. Thompson stated that Petitioner "developed sudden onset of back pain from cervical spine to sacrum" a week after receiving the flu vaccination on September 4, 2016. Id. at 1. "The pain was associated with progressive weakness of his shoulders, arms, hands, and proximal leg muscles; numbness involving his hands and feet; and profound fatigue." Id. Initial tests were normal, other than a low folate level which was supplemented. Id. Dr. Thompson referred Petitioner to a rheumatologist and a neurologist, but their testing "failed to reveal an etiology for his symptoms." Id. As such, Dr. Thompson stated "[n]o etiology has been found to explain [Petitioner's] persistent neurologic symptoms, other than the circumstantial evidence pointing to the fact his symptoms had their onset within days of receiving the seasonal [flu] vaccine." Id.

8. Letter from Dr. James Gore

Dr. Gore authored a letter signed August 27, 2020 stating, "I have read the letter written by Dr. John Thompson, dated [August 2, 2020]. I agree with the content and request of this letter." Pet. Ex. Q at 1.

Dr. Gore's medical records include emails from Petitioner asking Dr. Gore to sign, date, and mail the letter. Pet. Ex. U at 71, 73-74, 76-80.

9. Records of Gym Visits[37]

Records of Petitioner's gym visits to Franklin Recreation Center from January 1, 2015 to December 31, 2016 show that in June 2016, Petitioner visited the gym seven times. Pet. Ex. L at 1. In July 2016, he went to the gym three times, and in August 2016, he visited eight times. Id. at 1-2.

After his vaccination on September 4, 2016, the records show that Petitioner went to the gym three times in September 2016, six times in October 2016, and three times in November 2016. Pet. Ex. L at 2-3.

There are no records documenting visits in December 2016 or the first six months of 2017 (January 2017 through July 2017). See Pet. Ex. L. It does not appear that the search criteria used to identify Petitioner's visits to the gym included dates after December 31, 2016, as the inquiry was limited to dates from January 1, 2015 until December 31, 2016. Id. at 1. Therefore, it is not clear whether complete records for 2017 were produced.

Planet Fitness records show that Petitioner went to the gym six times in July 2017, and once in September, November, and December 2017. Pet. Ex. L at 13.

D. Expert Reports[38]

1. Petitioner's Expert, Dr. Curt Hagenau[39]

a. Background and Qualifications

Dr. Hagenau is a board-certified neurologist. Pet. Ex. R at 1. He received his M.D. from Vanderbilt University in 1982 after which he completed his internship in internal medicine, residency in neurology, and a fellowship in neurodiagnostic medicine at Vanderbilt University. Id. at 8. Dr. Hagenau works in private practice and has been in the general practice of adult neurology since 1987. Id. at 1, 8-9. Dr. Hagenau was formerly the Chief of the Department of Neurosciences at St. Thomas Midtown Hospital (formerly known as Baptist Hospital). Id. at 8. He was formerly a clinical instructor at the University of Tennessee Internal medicine residency

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[37] These records also show visits to Franklin Recreation Center from 2007 to 2015. See Pet. Ex. L at 4-10. These visits are not summarized herein, as they relate to earlier years. Only the visits in the year prior to and after vaccination are summarized, as they are deemed most relevant.

[38] The undersigned does not discuss the opinions of the experts related to small fiber neuropathy, as the parties' joint prehearing submission narrows the alleged vaccine related injury to FM. See Joint Submission at 2.

[39] Petitioner filed one report from Dr. Hagenau. Pet. Ex. R. Dr. Hagenau did not reference any medical literature in his expert report.

program where he also gave monthly lectures on numerous neurological topics including FM. Id. at 8-9.

b. Diagnosis Opinion

Dr. Hagenau opined that Petitioner has FM which is "the primary cause of his generalized pain and fatigability." Pet. Ex. R at 4. He further opined that Petitioner's condition is chronic, although it could improve with medication, "diet [,] and exercise." Id. Regarding alternative diagnoses, Dr. Hagenau opined that Petitioner did not have "a significant large fiber polyneuropathy" and "certainly does not have an inflammatory/demyelinating polyneuropathy." Id. at 5.

In reaching his opinions as to diagnosis, Dr. Hagenau reviewed Petitioner's medical records and performed a physical examination of Petitioner on March 5, 2021. Pet. Ex. R at 1. Physical examination revealed Petitioner to be "moderately overweight," with "mild to moderate pitting ankle edema." Id. at 4. His radial and pedal pulses were strong. Id. There was "[m]oderately diminished cervical range of motion, [n]o cranial tenderness," and "[m]ild diffuse thoracic, lumbar and limb tenderness." Id. Petitioner had normal strength throughout, and although he "mentioned weakness in his left hand, [his] finger spread and finger flexion/extension strength [was] normal." Id. Dr. Hagenau noted a "low amplitude rapid tremor [in] both outstretched hands" but no resting tremor. Id. Sensation in the hands and feet was normal. Id. Deep tendon reflexes were 2+ (on a scale of 4) at the elbow and 1+ at knees and ankles. Id. Petitioner had a "poor level of conditioning," but normal gait, and he was able to jog. Id. Neurological examination was normal. Id. Dr. Hagenau opined that Petitioner had "no excessive pain behavior[,]" and he did not "get the feeling that [Petitioner] was overstating his symptoms." Id.

Regarding the diagnosis of FM, Dr. Hagenau explained it is a common condition in middle-aged patients. Pet. Ex. R at 4. FM "produces a symptom complex of muscle aching and tenderness, with a feeling of heaviness and tiredness, even though actual muscle power is not diminished. As in [Petitioner's] case, it is often accompanied by diminished exercise intolerance, poor sleep quality, cognitive sluggishness, and abnormal skin sensations." Id.

c. Causation Opinion

i. Althen Prong One

According to Dr. Hagenau, the "primary problem in [FM] is dysfunction in the central pain pathways in the brain and spinal cord" which "become hyperactive, hypersensitive, generating the experience of pain, tingling or burning in areas of the body where there can be found nothing wrong peripherally." Pet. Ex. R at 5. Minor sensations are amplified into "painful sensations." Id. Moreover, "[the] dysfunction in the central and sensory pathways is often the cause of the peripheral tingling sensations." Id. FM patients are "predisposed to dysfunction in the tiny sensory nerve endings in the skin (small fiber sensory neuropathy)," although this "interaction between the central neurons and the peripheral neurons is not well understood." Id.;

see also Pet. Ex. DD.29 at 1(noting "the pathogenesis of FM is not fully understood, especially because compared to neuropathic conditions, in FM the source of sensory inputs is unknown").[40]

Dr. Hagenau opined that there can be a genetic predisposition to FM, as well as other predisposing factors, including "chronic anxiety, depression, and generally poor health and metabolic status." Pet. Ex. R at 5. An "acute trigger" may bring the "condition to the surface." Id. Examples of triggers include physical trauma, psychological trauma, [and] infectious trauma. Id. With infectious trauma trigger, "the body's inflammatory response to the microbe initiates persistent hyperactivity in the pain pathways and immune system." Id.

Dr. Hagenau opined that "[v]accinations, by design, induce an inflammatory response . . . to activate the immune system so that it will respond vigorously if exposed to the actual microbe . . . in the future." Pet. Ex. R at 5.

According to Dr. Hagenau, the lack of supportive studies to prove an association with vaccination is because "[c]hronic neurological syndromes" like FM caused by vaccination are rare and therefore, "it has been difficult for researchers to statistically prove a link through demographic studies between flu vaccination and [FM]." Pet. Ex. R at 5.

ii. Althen Prongs Two and Three

Before providing his opinions specific to causation in Petitioner's case, Dr. Hagenau briefly summarized Petitioner's course. Pet. Ex. R at 2-4. He noted that Petitioner received the flu vaccination on September 4, 2016, and then reported that "[five to seven] days after the vaccination[,] he acutely developed diffuse, intense[,] aching[,] [and] burning pain involving his upper, mid[,] and lower back," which was aggravated by movement. Id. at 2. The burning pain resolved over the next month, but Petitioner continued to experience "constant aching and tension," and "the aching pain spread to involve his limbs diffusely." Id. In the fall of 2016, Petitioner developed numbness and tingling in the hands and feet, fatigue with activity, and weakness. Id. at 3. He also had tremors in the hands, "heat and cold intolerance," mild temperature elevations, and "cognitive sluggishness/foggy headed feelings." Id.

Dr. Hagenau agreed that Petitioner "did not seek medical attention for his symptoms in the months after [] vaccination." Pet. Ex. R at 3. Petitioner did not report his FM symptoms to a physician, Dr. Thompson, until July 20, 2017. Id. Dr. Thompson's physical examination was normal and blood work was negative. Id. However, "Dr. Thompson felt that [Petitioner] had [FM]." Id.

Dr. Hagenau opined that Petitioner's flu vaccination on September 4, 2016 "contributed substantially to the development of his [FM]." Resp. Ex. R at 4.

As explained by Dr. Hagenau, DNA testing is not generally done in patients with FM, although there are some patients with a genetic predisposition to the illness. Pet. Ex. R at 5. In

[40] Simona D'Agnelli et al., Fibromyalgia: Genetics and Epigenetics Insights May Provide the Basis for the Development of Diagnostic Biomarkers, 15 Molecular Pain (2019).

addition to genetic predisposition, other contributing factors include physiological stressors, generally poor health, or metabolic status. Id. In Petitioner's case, Dr. Hagenau opined that "the psychological stress [] of losing his job in 2016, and his obesity and sleep apnea were predisposing factors." Id. Moreover, Petitioner had a "laboratory documented [flu] infection a few years previously, so it would be no surprise that he might have a vigorous immune response to the September 2016 [flu] vaccination." Id. This "resulted in activation of the nervous system and immune system that was long lasting and self-perpetuating thereafter, resulting in [Petitioner's] [FM]." Id.

Although Dr. Hagenau noted that the onset of Petitioner's symptoms occurred five to seven days after vaccination, he did not offer an opinion about whether such time frame was appropriate. See Pet. Ex. R at 2.

2. Petitioner's Expert, Dr. Omid Akbari, Ph.D.[41]

a. Background and Qualifications

Dr. Akbari is a Professor of Immunology and Professor of Medicine at the University of Southern California, Keck School of Medicine. Pet. Ex. DD at 2; Pet. Ex. EE at 2. He received a Ph.D. in cellular and molecular immunology at the National Institute for Medical Research in London, United Kingdom. Pet. Ex. EE at 1. Thereafter, he completed a postdoctoral fellowship at Stanford University. Id. Dr. Akbari's research focuses on the "the role of immune tolerance and how immune cells induce autoimmune and allergic diseases." Pet. Ex. DD at 2. His laboratory research includes multiple studies regarding how an "antigen, allergen, or vaccine can result in an appropriate or dysregulated immune response." Id. at 2-3. Dr. Akbari serves as an associate editor and reviewer on several journals. Id. at 2; Pet. Ex. EE at 4-5. He has authored or co-authored numerous publications. Pet. Ex. DD at 2; Pet. Ex. EE at 9-18. Dr. Akbari is not a medical doctor and is not qualified to diagnose or treat neurological conditions.

b. Diagnosis Opinion

Dr. Akbari did not offer any opinion about whether the diagnosis of FM was appropriate. As he is not a medical doctor, he limited his opinions to immunology and causation.

c. Causation Opinion

i. Althen Prong One[42]

[41] Petitioner filed two expert reports from Dr. Akbari. Pet. Exs. DD, GG.

Regarding the general question of whether vaccines can cause FM, Dr. Akbari opined that FM "is a heterogenous disease," involving environmental, infectious, and genetic predispositions, and that "induction of inflammasome[43] by vaccines play an important role as [an] initial trigger" for development of the illness. Pet. Ex. DD at 8; Pet. Ex. GG at 2-5. In addition to his hypothesis based on inflammasomes, Dr. Akbari offered several different theories of causation in his expert reports.

Early in his initial expert report, Dr. Akbari addressed the question of whether FM is an immune mediated illness. Pet. Ex. DD at 5. He opined that FM is immune mediated and that both the innate[44] and adaptive[45] immune systems are involved in its development. Id. at 5-6. Starting with the innate immune system, Dr. Akbari suggested "that [FM] could involve

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[42] Due to relevance and for the sake of brevity, the undersigned has not summarized large sections of Dr. Akbari's initial report which discuss Petitioner's clinical course and general principals of immunology. See Pet. Ex. DD at 3-7. Additionally, the undersigned does not discuss Dr. Akbari's explanation of self-tolerance or the regulatory T cells and their role in the induction of autoimmune diseases. Id. at 7-8. The undersigned also does not discuss how viruses activate the inflammasome pathway or the pattern recognition receptors. Id. at 10, 12. Nor is the possibility of Rubella vaccination causing FM or the study of rare diseases and adverse effects discussed. Id. at 19, 22-24. Instead, the undersigned has focused on the principal causal hypotheses advanced by Dr. Akbari.

[43] "Inflammasomes function as immune-signaling platforms that assemble following pathogen detection." Pet. Ex. DD.14 at 1 (Ella Hartenian & Petr Broz, Viral Protein Activates the NLRP1 Inflammasome, 23 Nature Immunology 818 (2022)). Inflammasomes are "a complex of cryopyrin, caspase-1, and other proteins, found in phagocytic cells and related to the body's system of innate immunity. Assembly of the inflammasome leads to activation of caspase-1 and resultant cleavage and activation of interleukins IL-1β and IL18 in the inflammatory response." Inflammasome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25203 (last visited Oct. 2, 2024).

[44] The innate immune response is immunity that "does not require prior exposure to an antigen (i.e. immunological memory) to be fully effective. . . . Components include Phagocytic cells (e.g. neutrophils, monocytes, macrophages)[,] Polymorphonuclear leukocytes (in addition to phagocytic neutrophils, including eosinophils and basophils)[,] [and] Innate lymphoid cells . . . ." Peter J. Delves, Overview of the Immune System, Merck Manual, https://www.merckmanuals.com/professional/immunology-allergic-disorders/biology-of-the-immune-system/overview-of-the-immune-system (last visited Oct. 14, 2024).

[45] The adaptive immune response is immunity that "requires prior exposure to an antigen to be fully effective and takes time to develop after the initial encounter with a new invader. Thereafter, response is quick. The system remembers past exposures and is antigen-specific. Components include B cells [and] T cells." Delves, supra note 44.

localized inflammation" due to increased levels of "proinflammatory cytokines[46] and chemokines[47] . . . in the serum and cerebrospinal fluid" of patients with the illness. Id. at 5. He explained that cytokines (IL-8, IL-1β, TNFα, IL-6, and IL-17) "could contribute to the inflammatory response" in the central nervous system ("CNS") and that the "pain in [FM] involves neuroinflammatory processes triggered by mast cells[48] and microglia."[49] Id. at 6. He further stated that research studies "underline the role of cells and mediators of innate immunity in maintaining pain conditions such as musculoskeletal pain and central sensitization."[50] Id.

Regarding his opinion that cytokines and chemokines play a causal role in FM, Dr. Akbari cited a study by Garcia et al. Pet. Ex. DD at 6 (citing Pet. Ex. DD.6). The purpose of the study was to compare chemokine profiles of patients with FM (17 patients) as compared to healthy controls (10 controls). Id. at 2-3. The FM patients had increased serum levels of some inflammatory chemokines, but no differences in others.[51] Id. at 3. While the research suggested that "an inflammatory state may contribute to pain[,]" additional research was recommended to determine the role of chemokines in FM pathogenesis. Id. at 5.

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[46] Cytokine is "a generic term for nonantibody proteins released by one cell population (e.g., primed T lymphocytes) on contact with a specific antigen, which act as intercellular mediators, as in the generation of an immune response." Cytokine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=12428 (last visited Oct. 2, 2024).

[47] Chemokines are "a family of low-molecular-weight (8–10 kD) cytokines that induce chemotaxis or chemokinesis in leukocytes . . . . Chemokines are regulators of the immune system and may also play roles in the circulatory and central nervous systems." Chemokine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=9024 (last visited Oct. 2, 2024).

[48] Mast cell is "a type of migrant connective tissue cell with basophilic, metachromatic, cytoplasmic granules that contain histamine and heparin in humans." Mast Cell, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=64240 (last visited Oct. 2, 2024).

[49] Microglia are "the small, nonneural, interstitial cells of mesodermal origin that form part of the supporting structure of the central nervous system. . . . They are migratory and act as phagocytes to remove waste products of nerve tissue." Microglia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=31308 (last visited Oct. 2, 2024).

[50] Central sensitization is "a proposed mechanism for the cause of chronic pain conditions and migraine, by which nociceptors in the [CNS] become hypersensitive to stimuli as a result of tissue damage or inflammation." Central Sensitization, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=105522 (last visited Oct. 2, 2024).

[51] Garcia et al. provided an overview of chemokines, and discuss the three families of chemokines, including those with "pro-inflammatory, homoeostasis[,] and mixed function." See Pet. Ex. DD.6 at 2.

After discussing cytokines and chemokines, Dr. Akbari moved to the topic of inflammasomes. He opined that inflammasomes are activated after flu infection and vaccination, citing a study by Crooke et al.[52] in support of this proposition. Pet. Ex. DD at 8 (citing Pet. Ex. DD.11); Pet. Ex. GG at 2-3. Crooke et al. studied the blood tests of 147 adults separated into two age groups, young (aged 18-39) and old (age 65-92), pre- and post-flu vaccination. Pet. Ex. DD.11 at 1. Post-vaccination testing was done at 24 hours and 28 days. Id. at 2. There was no significant age-related differences seen in inflammasome activity in macrophages. Id. at 9. Of note, the authors stated that "inflammasome has been implicated as a critical component for protective immunity after [flu] in several animal studies," although this phenomenon has not been studied in humans. Id. Although the study confirmed that inflammasomes are present after flu vaccination, it did not describe any adverse effects related to these inflammasomes, rather the focus of the research was on the protective immunity aspect of inflammasomes. See id. at 2.

Moreover, the Crooke et al. study did not show that inflammasomes were responsible for the decreased immune response to the flu vaccine in older adults. Pet. Ex. DD.11 at 8. The studies showed that P2XR7 gene[53] expression was lower in blood samples from older adults, and that "lower expression of P2XR7 would be expected to result in decreased inflammasome activation," but they did not observe such a decline. Id. at 8-9. Thus, the researchers concluded there were other factors that accounted for the "the decreased expression of P2XR7 or that an alternative mechanism unaffected by age is responsible for stimulating inflammasome following [flu] vaccination." Id. at 8-9.

After citing Crooke et al. for the proposition that inflammasomes are present after flu vaccination, Dr. Akbari asserted that inflammasomes "play[] an important role" in inducing FM. Pet. Ex. DD at 11. In support of this aspect of his opinion, Dr. Akbari cited to articles by Cordero et al.[54] and D'Amico et al.[55] Id. at 11-12 (citing Pet. Exs. DD.15, DD.16). Cordero et. al. observed that previous studies have suggested that mitochondrial dysfunction and inflammasome activation may be associated with FM. Pet. Ex. DD.15 at 1-2. The authors

[52] Stephen N. Crooke et al., Inflammasome Activity in Response to Influenza Vaccination Is Maintained in Monocyte-Derived Peripheral Blood Macrophages in Older Adults, 2 Frontiers Aging 1 (2021).

[53] The P2XR7 gene "encodes the purinergic receptor P2X7, which senses extracellular concentrations of adenosine triphosphate and has been identified as one of the major drivers of inflammasome activation." Pet. Ex. D.11 at 8.

[54] Mario D. Cordero et al., NLRP3 Inflammasome Is Activated in Fibromyalgia: The Effect of Coenzyme Q_{10}, 20 Antioxidants & Redox Signaling 1169 (2014).

[55] Romana D'Amico et al., Inhibition of P2X7 Purinergic Receptor Ameliorates Fibromyalgia Syndrome by Suppressing NLRP3 Pathway, 22 Int'l J. Molecular Sci. 6471 (2021).

studied the role of coenzyme Q_{10} ("CoQ10") deficiency[56] and mitochondrial dysfunction in inflammasome activation in FM. Id. at 2. They found that mitochondrial dysfunction occurred with an increase in protein expression of interleukins (IL)-1β, NLRP3 inflammasome, and caspase-1 as well as an increase in proinflammatory cytokines (IL-1β and IL-18). Id. at 2, 4. The authors concluded that the results established an important role for inflammasome NLRP3 in the etiology of FM and suggested that inflammasome inhibition was a potential for treatment of the illness. Id. at 1. But they did not conclude that vaccination-induced inflammasomes were a mechanism that induce FM. See id. at 4-5.

D'Amico et al., published more recently in 2021, addressed the role of nociceptors[57] in the etiology of FM. Pet. Ex. DD.16. At the outset, the authors acknowledged that despite significant developments in the understanding of FM, "the etiology . . . is still unknown." Id. at 1. They noted that "there is evidence that FM is associated with disturbances in pain processing by the [CNS]." Id. The authors suggested that the immune system and neuroinflammation may play a role in this sensitization process, by activating nociceptors. Id. Nociceptors are, in turn, "triggered by proinflammatory mediators such as [ATP] [58] or interleukin-1β (IL-1β)." Id. at 1-2. The authors describe the nociceptive transmission system, which involves "the P2X7 receptor" and "ATP-gated ion channel[59] that play an important role in the inflammatory response and in different pain states." Id. at 2. The P2X7 receptor is "overactivated due to ATP release, resulting in anion imbalance and triggering of microglia, that additionally exacerbate cell damage." Id. Further, they explain that "P2X7R activation is involved" in signaling "the

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[56] CoQ10 is "an antioxidant, produced naturally in humans, that is also a cofactor for mitochondrial adenosine triphosphate (ATP) generation. The levels of CoQ10 seem to be lower in older people and in people with chronic diseases . . . ." Laura Shane-McWhorter, Coenzyme Q10 (CoQ10), Merck Manual, https://www.merckmanuals.com/professional/special-subjects/dietary-supplements/coenzyme-q10-coq10?query=coenzyme%20q10%20(coq10) (last visited Oct. 24, 2024).

[57] Nociceptors are "a receptor for pain caused by injury to body tissues." Nociceptor, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=34263 (last visited Oct. 2, 2024).

[58] ATP is "a nucleotide, the 5′-triphosphate of adenosine, involved in energy metabolism and required for RNA synthesis; it occurs in all cells and is used to store energy in the form of high-energy phosphate bonds." Adenosine Triphosphate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=54993 (last visited Oct. 2, 2024).

[59] Ion channel is "a cell membrane protein with an ion-specific transmembrane pore, through which ions and small molecules pass into or out of a cell by diffusion downward along their electrochemical gradient; although some are always open, most open and close in response to a stimulus. Movement of ions through channels controls the electrical potential across the membrane and plays a vital role in depolarization and repolarization of nerve and muscle fibers." Ion Channel, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=64836 (last visited Oct. 2, 2024).

NLRP3 inflammasome pathway,"[60] and the release of IL-1β and IL-18, which "mediate painful conditions." Id.

The specific purpose of the D'Amico et al. study was to determine whether Brilliant Blue G ("BBG"), a P2X7R antagonist, could block P2X7R in rats with reserpine[61]-induced FM. Pet. Ex. DD.16 at 2. They found that BBG significantly decreased P2X7R expression. Id. NLRP3 levels were also notably reduced in the animals that received BBG. Id. at 4. However, the study did not examine whether the flu vaccination activated the nociceptive transmission system, the ATP-gated ion channel, the NLRP3 inflammasome pathway, or otherwise induced FM. See id.

Next, Dr. Akbari proposed that Th17 cells[62] play a role in causing FM because they are "potent inducers of tissue inflammation" associated with many autoimmune conditions, including FM. Pet. Ex. DD at 12; Pet. Ex. GG at 4. He cited Pernambuco et al.,[63] who explained that Th17 lymphocytes produce the cytokine IL-17A. Pet. Ex. DD.18 at 2. The authors reported elevated levels of IL-17A in 58 patients with FM as compared to 39 healthy controls. Id. at 1. These findings "strengthened the hypothesis of inflammatory mechanisms" in the development of FM. Id. at 2. However, the paper included a caveat, noting that IL-17A was produced not only by Th17 lymphocytes, but also by natural killer cells, dendritic cells, and neutrophils, and the study did not address the origin of IL-17A found in the FM patients. See id. Thus, the study only showed that IL-17A was "possibly produced" by activated T lymphocytes (Th17 cells). Id. The study did not show that vaccination triggered activation of Th17 cells which caused inflammation that triggered FM. See id.

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[60] An NLRP3 inflammasome is a multi-protein complex which "includes NLRP3, a NOD-like receptor that is a sensor for the activation of the inflammasome, an apoptosis-associated speck-like protein containing a CARD complex (ASC), and the serine protease caspase 1 (Casp-1). The activation of NLRP3 leads to the maturation of Casp-1, which is subsequently implicated in the cleavage of pro-IL-1 β and pro-IL-18 into the biologically active cytokines." Pet. Ex. DD.16 at 8-9; see supra note 43 (defining inflammasome).

[61] Reserpine is "an alkaloid isolated from the root of Rauwolfia serpentina and other species of Rauwolfia." Reserpine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com /dorland/definition?id=43397 (last visited Oct. 2, 2024). Reserpine has been used in preclinical research for many years to create animal models including for depression and Parkinson's disease. See, e.g., Lidia Telega et al., Reserpine-Induced Rat Model for Depression, 133 Progress Neuro-Psychopharmacology & Biological Psychiatry 111013 (2024).

[62] Th17, or T helper 17 cells, are a "distinct lineage of T cells that produce the effector molecules IL-17, IL-17F, IL-21 and IL-22." Pet. Ex. DD.24 at 1 (Yinyao Lin et al., Th17 Cytokines and Vaccine Induced Immunity, 32 Seminars Immunopathology 79 (2010)); see also infra note 65 (defining T cells).

[63] A.P. Pernambuco et al., Increased Levels of IL-17A in Patients with Fibromyalgia, 31 Clinical & Experimental Rheumatology S-60 (2013).

Continuing with the theme of Th17 cells, Dr. Akbari explained that the flu vaccination "increases the level of IL-17 and Th17 cells" for the purpose of creating "effective long-lived vaccine induced immunity against viruses." Pet. Ex. DD at 13. He asserted that in some patients, "Th17 induced by [the] flu vaccine is capable of inducing FM." Id. He cited two papers to support this opinion. Id. The first is by Bermejo-Martin et al.,[64] which discussed Th17 secretion in the context of H1N1 flu infection. See Pet. Ex. DD.23. The article does not discuss vaccination, and Dr. Akbari does not show that the flu vaccination is comparable to the H1N1 infection so as to make the results of the study applicable here.

The second paper by Lin et al., does discuss vaccination and the role of Th17 and IL-17 in "vaccine-induced memory immune responses" but does not discuss their role in inducing FM. Pet. Ex. DD.24 at 1. Although IL-17 can protect against infections, the authors also discussed the potential for pathological consequences, such as tissue destruction seen in models of certain diseases ("arthritis, multiple sclerosis, and colitis"). Id. FM is not discussed, and the paper does not stand for the proposition that IL-17 plays a role in the development of FM. See id.

Moving to another theory, Dr. Akbari discussed the importance of T cells,[65] citing a study by Ganor et al.[66] Pet. Ex. DD at 6 (citing Pet. Ex. DD.4). The authors stated that T cells in the CNS in various brain diseases may cause and/or augment pathology. Pet. Ex. DD.4 at 1. One example is T-cell-mediated encephalomyelitis in multiple sclerosis. Id. In this context, T cells "could possibly encounter glutamate," a "the major excitatory neurotransmitter in the [CNS]," that mediates "most of the excitatory transactions between CNS neurons." Id. The authors hypothesize that T cells "could possibly encounter glutamate" in traumatic brain injury, stroke, epilepsy, meningitis, and brain neurodegenerative diseases like MS, amyotrophic lateral sclerosis ("ALS"), and Alzheimer's disease. Id. They do not identify FM as an illness in which T cells could encounter glutamate, and the article does not mention FM. See id.

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[64] Jesus F. Bermejo-Martin et al., Th1 and Th17 Hypercytokinemia As Early Host Response Signature in Severe Pandemic Influenza, 13 Critical Care R201 (2009).

[65] T cells are "the cells primarily responsible for cell-mediated immunity; they originate from lymphoid stem cells that migrate from the bone marrow to the thymus and differentiate under the influence of the thymic hormones thymopoietin and thymosin. . . . T cell antigen receptors are triggered by antigen only when associated with self MHC antigens, e.g., by antigens processed and presented by macrophages, viral antigens on the surface of host cells, and tumor neoantigens. When activated by antigen, T lymphocytes proliferate and differentiate into T memory cells and the various types of regulatory and effector T cells. T Cells, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=87562 (last visited Oct. 2, 2024).

[66] Yonatan Ganor et al., Human T Cells Express a Functional Ionotropic Glutamate Receptor GluR3, and Glutamate by Itself Triggers Integrin-Mediated Adhesion to Laminin and Fibronectin and Chemotactic Migration, 170 J. Immunology 4362 (2003).

Another paper cited by Dr. Akbari[67] to emphasize the role of T cells, authored by Kaufmann et al.,[68] was a study of complex regional pain syndrome ("CRPS") and FM. Pet. Ex. DD.5 at 1. The authors studied 22 patients with FM and 15 patients with CRPS compared to 37 healthy controls and found that "[l]ymphocyte numbers did not differ between the groups." Id. However, "lymphocyte subpopulations showed a significant reduction of cytotoxic CD8+ lymphocytes" in both CRPS and FM patients as compared to the control group. Id. The authors were unable to determine whether the reduction in the lymphocyte subpopulation was due to a pathogenic role or "merely reflect the consequences of a pain-induced neurohumoral stress response." Id. Further research was recommended. Id. The study did not establish that vaccination or T cells play a role in the cause of FM. See id.

Next, Dr. Akbari moved to his hypothesis about the role of regulatory T cells ("Tregs")[69] in causing FM. Pet. Ex. DD at 14; Pet. Ex. GG at 5. He discussed the concept of self-tolerance and the role of regulatory T cells in "maintaining tolerance to self-antigens and abrogating autoimmune disease." Pet. Ex. DD at 7. He stated that a decrease in T regulatory cells results in a predisposition to develop an autoimmune illness. Id. at 7-8, 14. According to Dr. Akbari, regulatory T cells could exert "suppressive activity by secreting a variety of cytokines including a major immune suppressor cytokine, IL-10." Id. at 14.

Dr. Akbari stated that regulatory T cells also produce IL-10. Pet. Ex. DD at 15. He cited a study by Andrés-Rodríguez et al.,[70] which "concluded that IL-10 is the best predictor of [a] FM diagnosis." Pet. Ex. DD at 14 (citing Pet. Ex. DD.26). The authors found lower levels of anti-inflammatory cytokines IL-4 and IL-10 in patients who had chronic pain. Pet. Ex. DD.26 at 1. Based on these findings, Dr. Akbari suggested another hypothesis, which "combines the effects of lowered IL-10 and IL-6 in explaining FM symptoms." Pet. Ex. DD at 14. This hypothesis, however, seems to ignore the conclusion of the authors, that "[a]ll in all, the results show there is a large heterogeneity among studies in cytokine-chemokine results," and that "the immune profile observed . . . indicate[d] there is no clear immune activation and no inflammatory

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[67] Dr. Akbari discussed another study about the role of T cells in his expert report, which was "performed on 65 patients with FM, [and] that showed a decrease in CD3+T cells." Pet. Ex. DD at 6. However, Dr. Akbari did not provide a reference for this study.

[68] Ines Kaufmann et al., Lymphocyte Subsets and the Role of Th1/Th2 Balance in Stressed Chronic Pain Patients, 14 Neuroimmunomodulation 272 (2007).

[69] Regulatory T cells, or Tregs, are "a subset of CD4+ T cells that can suppress activity of effector cells such as helper cells and suppressor cells, and inhibit autoimmune diseases." Regulatory T Cells, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition? id=64383 (last visited Oct. 2, 2024); see also Pet. Ex. DD.9 (Christian Dejaco et al., Imbalance of Regulatory T Cells in Human Autoimmune Diseases, 117 Immunology 289 (2005) (providing a technical discussion of the imbalance of Tregs in autoimmune illnesses).

[70] Laura Andrés-Rodríguez et al., Machine Learning to Understand the Immune-Inflammatory Pathways in Fibromyalgia, 20 Int'l J. Molecular Sci. 4231 (2019).

response (according to [the] classic biomarkers)" in the FM group studied. Pet. Ex. DD.26 at 8-9.

After discussing regulatory T cells, Dr. Akbari turned to MTHFR gene mutations and their role in "disease risk after vaccination." Pet. Ex. DD at 16; Pet. Ex. GG at 7-8. He explained that MTHFR is a critical enzyme required "for a metabolic process that repairs DNA, switches genes on and off," among other things, and is "essential to convert folate and folic acid . . . into the biologically active form called L-methyl folate." Pet. Ex. DD at 16. MTHFR mutations have been linked with "disorders affecting the immune system and causing inflammation and autoimmunity." Id. Dr. Akbari asserted that these mutations have been associated with post-vaccination adverse effects. Id. at 17. After a summary of two clinical trials related to MTHFR genetic mutations, he concluded that "a comprehensive clinical trial is required to determine the association between adverse effects after flu vaccination in patients with MTHFR mutation." Id. at 17-18. He did not conclude that the mutation played a role in causing FM after flu vaccination.

The next subject raised by Dr. Akbari was the role of EBV infection in the pathogenesis of FM. Pet. Ex. DD at 18; Pet. Ex. GG at 9-10. He observed that the symptoms of FM "overlap considerably with those of a viral [] infection." Pet. Ex. DD at 18. These symptoms include fatigue, sore throat, rash, adenopathy, and recurring low-grade fever. Id. Dr. Akbari posited that EBV and FM are related, "due to the similarity of symptoms and immune response of [FM] to infectious agents." Id. But he asserted that "EBV cannot cause [FM] alone," since EBV infections affect "more than 90%" of the world population, and FM is not as prevalent. Id. at 19. According to Dr. Akbari, "the development of FM requires another trigger such as the flu vaccine with the capability of inducing inflammasome." Id. Dr. Akbari, however, did not conclude that the flu vaccine can cause FM in a patient with an EBV infection.

Regarding any specific association between the flu vaccination and FM, Dr. Akbari stated that "although current data are insufficient in order to establish a definite relationship between flu vaccination and [FM], it appears clear that this vaccine is capable of causing acute FM including musculoskeletal symptoms and certainly the frequency and induction of FM cannot be ruled out after flu vaccination." Pet. Ex. DD at 21. Here, Dr. Akbari agreed that current information does not establish a causal association between the flu vaccination and FM, but he is unable to rule out a casual association between flu vaccination and FM. Id. However, an inability to rule out vaccination as a cause does not reach the preponderant standard of more likely than not. See infra section V.A (discussing legal standards for causation).

Some of the medical articles cited by Dr. Akbari do not relate to FM but are about polymyalgia and polymyalgia rheumatica ("PMR").[71] A study by Falsetti et al. reviewed the triggers of PMR in 58 patients, finding that six patients reported vaccination before onset of symptoms, including four patients who had a flu vaccine. Pet. Ex. DD.25 at 3. The study did

[71] PMR is "a common condition characterized by inflammatory pain and stiffness in the shoulder and in the pelvic girdle and neck." Pet. Ex. DD.25 at 1 (Paolo Falsetti et al., Polymyalgia Rheumatica Following Infective Triggers or Vaccinations: A Different Subset of Disease?, 58 Rheumatologia 76 (2020)).

not include patients with FM. See id. In citing this article in his expert report, Dr. Akbari stated that the six patients who reported vaccination prior to onset of symptoms had FM. Pet. Ex. DD at 20. This statement is incorrect. The authors stated that the six patients had PMR, not FM. Pet. Ex. DD.25 at 3. Dr. Akbari did not cite any evidence to show that PMR and FM are the same or similar disease.

Dr. Akbari also cited several case reports of patients who he asserts developed FM after flu vaccinations, but again, he is incorrect. The articles refer to PMR, not FM. See Pet. Ex. DD at 21 (citing to Pet. Ex DD.39 (discussing PMR after flu vaccination);[72] Pet. Ex. DD.40 (same);[73] Pet. Ex. DD.41(same)).[74]

Dr. Akbari dismissed the value of the 2015 Ablin et al.[75] study cited by Respondent's expert, Dr. Jamieson, which found the flu vaccine safe for patients with FM on the basis that the study was conducted to address the safety of vaccination in patients with established FM, not whether the vaccination could cause FM. Pet. Ex. DD at 21. He also distinguished the article on the basis that it did not consider the importance of MTHFR genetic mutations. Id.

Dr. Akbari concluded by stating that he showed "numerous ways in which the scientific evidence supports the biological mechanisms by which an immune-stimulated response to the flu vaccination is able to trigger immune cells that cause inflammatory diseases such as FM." Pet. Ex. DD at 26.

ii. Althen Prongs Two and Three

Dr. Akbari opined that "to a reasonable degree of scientific certainty, and by [] preponderant evidence, had it not been for the flu vaccination, [Petitioner] would not have developed FM." Pet. Ex. DD at 26. He further opined that the "onset of symptoms following the flu vaccine support that . . . the flu vaccine administered on September 4, 2016[] resulted in the onset of headache and FM." Id. According to Dr. Akbari, an onset of seven days is "textbook." Id. at 27. Specific to Petitioner's MTHFR genetic mutation, Dr. Akbari opined that the onset time was consistent with the development of FM in patients with these mutations. Id. at 26-27.

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[72] A. Soriano et al., Giant Cell Arteritis and Polymyalgia Rheumatica After Influenza Vaccination: Report of 10 Cases and Review of the Literature, 21 Lupus 153 (2012).

[73] Eric Liozon et al., Polymyalgia Rheumatica Following Influenza Vaccination, 48 J. Am. Geriatric Soc'y 1533 (2000).

[74] Carlos Perez & Ellas Maravl, Polymyalgia Rheumatica Following Influenza Vaccination, 23 Muscle & Nerve 824 (2000).

[75] Jacob N. Ablin et al., Influenza Vaccination Is Safe and Effective in Patients Suffering from Fibromyalgia Syndrome, 67 Reumatismo 57 (2015) (cited as Resp. Ex. A, Tab 9).

However, regarding his theory based on the "induction of inflammasome by innate immune cells," Dr. Akbari opined that onset would be "relatively fast" and the peak response would be in one to three days. Pet. Ex. DD at 26.

While Dr. Akbari opined that Petitioner's "initial symptoms of FM were noticeable and significant" a week after vaccination, he noted that it took several months for Petitioner to receive the appropriate diagnosis of FM. Pet. Ex. DD at 27. But he disagreed with Dr. Jamieson that it took Petitioner ten months to develop FM after vaccination. Id.

3. Petitioner's Expert, Dr. Joseph S. Jeret[76]

a. Background and Qualifications

Dr. Jeret is a board-certified neurologist. Pet. Ex. BB at 1; Pet. Ex. CC at 1. He received his medical degree from SUNY Downstate Medical Center. Pet. Ex. BB at 1. He did a general internal medicine internship at Maimonides Medical Center followed by a residency in neurology and a fellowship in clinical neurophysiology at SUNY Downstate. Id. at 1. Dr. Jeret is a practicing neurologist. Id. at 1-2. He works as a physician at the Icahn School of Medicine and maintains an active neurology practice in Long Island, NY. Id. He routinely cares for and diagnoses patients with various neurological illness including FM and small fiber neuropathy. Id. at 2. Dr. Jeret has authored or co-authored publications in many areas of neurology reflecting his general neurology practice. Id.; Pet. Ex. CC at 2-7.

b. Diagnosis Opinion[77]

At the outset, Dr. Jeret explained that FM is characterized by widespread pain. Pet. Ex. BB at 4. Diagnostic criteria established by the ACR in 1990 included the patient's complaint of widespread pain as well as "pain on digital palpation in 11 of 18 specific locations." Id. Dr. Jeret explained that these criteria were rigid because a finding of only "10 tender spots" did not meet the criteria, whereas 11 or more did. Id. Further, the examiner had to apply "approximately 4 kg of pressure" during the evaluation or the results were invalid. Id.

Dr. Jeret opined that Petitioner's diagnosis of FM satisfied the 2010 ACR diagnostic criteria, which used the WPI and symptom severity score for three symptoms of fatigue, waking unrefreshed, and cognitive symptoms. Pet. Ex. BB at 9-10. Even if the criteria were not satisfied, Dr. Jeret opined that the diagnosis of FM was appropriate because Petitioner's treating physicians, Drs. Thompson, Kalf, and Chothmounethink, diagnosed Petitioner with FM. Id. at 10.

To diagnose a patient with FM, Dr. Jeret explained that "the history provided by the patient is all that is needed." Pet. Ex. BB at 9. Based on his review of Petitioner's medical

[76] Petitioner filed two expert reports from Dr. Jeret. Pet. Exs. BB, FF.

[77] In his expert report, Dr. Jeret stated that all of his opinions are held to a "reasonable degree of medical certainly except where noted otherwise." Pet. Ex. BB at 13.

records, Dr. Jeret identified documentation of 13 instances of pain in Petitioner's extremities, buttocks, legs, back, and neck. Id. at 10. Therefore, he assessed Petitioner's WPI score as 13. Id. Next, Dr. Jeret assessed symptom severity, again, based on the medical records, and determined that Petitioner scored 7 to 9 points due to fatigue, waking unrefreshed, cognitive symptoms, and somatic symptoms. Id. Given a WPI index of 13 points and a SS score of at least 7 points, Dr. Jeret opined that Petitioner met the 2010 ACR diagnostic criteria for FM. Id. Dr. Jeret opined there was no other diagnosis made to explain Petitioner's symptoms. Id. Therefore, he concluded that Petitioner met the ACR diagnostic criteria for FM. Id.

Dr. Jeret explained that although Petitioner's treating physicians did not use the "strict ACR checklist," they did reach a diagnosis of FM. Pet. Ex. BB at 10-11. He agreed it was "appropriate for a clinician to diagnose [FM] even if the strict criteria [were] not satisfied." Id. at 10. This approach incorporates the "real world" practice where physicians often reach a diagnosis even if strictly speaking, diagnostic criteria are not met. Id. at 6. Further, Dr. Thompson documented that Petitioner had "symmetric trigger points over classic [FM] sites." Id. at 10. Based on this note, Dr. Jeret presumed Dr. Thompson thought Petitioner satisfied the 1990 ACR criteria,[78] although he acknowledged that "detail [was] certainly lacking in [Dr. Thompson's] note." Id.

Dr. Jeret also reviewed Petitioner's clinical course, and the onset of his FM symptoms. Dr. Jeret noted that on June 13, 2017, Dr. Thompson did not identify FM as a diagnosis. Pet. Ex. BB at 7. On June 24, 2017, Petitioner saw a chiropractor, Dr. Gil, and at that visit Petitioner completed an intake form, stating that he had "pain in his neck, shoulder, upper back, midback, low back, hip, and legs." Id. (citing Pet. Ex. J at 2-3). Then on July 20, 2017, Petitioner reported to Dr. Thompson that he had "aches all over his body: thighs, back, neck, [and] hands . . . since September 12, 2016." Id. At this visit, Dr. Thompson included FM as a diagnosis in Petitioner's medical records. Id.

In his second expert report, Dr. Jeret took issue with some of the opinions of Respondent's expert, Dr. Jamieson. See Pet. Ex. FF at 1-2. While Dr. Jamieson asserted that since Petitioner's neurologist and rheumatologist did not diagnose Petitioner with FM suggested that he did not have FM, Dr. Jeret stated that these doctors did not apply the diagnostic criteria for FM when they examined Petitioner. Id. at 1-2. When Dr. Jeret retroactively applied the criteria, he was able to make the diagnosis of FM. Id. at 2.

c. Causation Opinion

i. Althen Prong One

Dr. Jeret opined that "[o]ccasionally, the immune system 'gets the wrong message' and will attack an unintended target by creating an autoimmune response." Pet. Ex. BB at 11. This phenomenon is called "molecular mimicry due to the similarity of the body's own peptides to the foreign peptides in the vaccine." Id. He explained this "same immune error" is the mechanism

[78] Dr. Jeret discussed the 1990 ACR criteria for FM in his initial report which include "widespread pain and pain on digital palpation in 11 of 18 specific locations." Pet. Ex. BB at 4.

responsible for Guillain-Barré syndrome ("GBS")[79] after flu vaccination, which he referenced as "a well-recognized phenomenon." Id.; see Pet. Ex. BB.12 (describing molecular mimicry as an implicated mechanism for vaccine-related autoimmunity in numerous conditions, including GBS but not FM).[80]

According to Dr. Jeret, FM "has an immune basis." Pet. Ex. BB at 11. He cited research by Goebel et al.,[81] published in 2021, showing that serum Immunoglobulin ("Ig") G[82] from FM patients injected into mice caused them to have "painful sensory hypersensitivities," "increased cold sensitivity," and decreased activity. Id. (citing Pet. Ex. BB.5 at 1-5). Of note, the serum IgG injected into mice from FM patients did not "induce cytokine production or systemic inflammation." Pet. Ex. BB.5 at 6. The authors concluded that passive transfer of serum IgG from FM patients did not "alter systemic inflammatory and immunomodulatory cytokine levels." Id. at 6-7.

Regarding other proposed mechanisms by which the flu vaccination can cause FM, Dr. Jeret referred to Dr. Akbari's expert reports. Pet. Ex. BB at 11. Dr. Jeret noted "there are often multiple factors at play—so it is hard to 'tease out' the role of a vaccine." Id. He cited a review article by Ablin et al.,[83] which stated that "[m]ultiple putative triggers have been implicated" in the pathogenesis of FM, including infections, chronic Lyme disease, mycoplasma, and human immunodifiency virus ("HIV"). Pet. Ex. BB.1 at 1. The authors suggested that multiple factors, including multiple vaccinations, along with other risk factors may possibly play a role in

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[79] Guillain-Barré syndrome ("GBS") "is an acute/subacute onset polyradiculoneuropathy typically presenting with sensory symptoms and weakness over several days." Pet. Ex. BB.3 at 1 (Peter D. Donofrio, Guillain-Barré Syndrome, 23 Continuum 1295 (2017)). NCS "show evidence for a multifocal demyelinating process." Id. Dr. Jeret filed several articles about GBS and CIDP, a demyelinating process and/or process that causes axonal injury. See, e.g., Pet. Ex. BB.6 (Kenneth C. Gorson & Allan H. Ropper, Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP): A Review of Clinical Syndromes and Treatment Approaches in Clinical Practice, 4 J. Clinical Neuromuscular Disease 174 (2003)); Pet. Ex. BB.7 (Penina Haber et al., Vaccines and Guillain-Barré Syndrome, 32 Drug Safety 309 (2009)). There is no evidence filed in this case which shows FM is caused by a similar immune process or that it is a demyelinating process or axonal injury like GBS or CIDP.

[80] Yahel Segal & Yehuda Shoenfeld, Vaccine-Induced Autoimmunity: The Role of Molecular Mimicry and Immune Crossreaction, 15 Cellular & Molecular Immunology 586 (2018).

[81] Andreas Goebel et al., Passive Transfer of Fibromyalgia Symptoms from Patients to Mice, 131 J. Clinical Investigation e144201 (2021).

[82] Immunoglobulin G, or IgG, is one class of "glycoproteins that function as antibodies." Immunoglobulin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=24894 (last visited Oct. 22, 2024).

[83] Jacob N. Ablin et al., Fibromyalgia, Infection and Vaccination: Two More Parts in the Etiological Puzzle, 27 J. Autoimmunity 145 (2006).

initiating Gulf War syndrome,[84] which has some features in common with FM. Id. The authors noted, however, that the cause of FM is "yet unclear." Id. They also noted that "[FM] is generally not considered an autoimmune disorder." Id. at 2. After reviewing studies about associations between infections and FM, they concluded that any association "remains obscure." Id. at 5. They also stated that "the possible relationship of [FM] with vaccination similarly remains to be established." Id.

Dr. Jeret concluded his discussion about the pathogenesis of FM by quoting from Buskila et al.: "There is some anecdotal evidence for the role of vaccination in the development of FM[], but more studies are needed to confirm this association." Pet. Ex. BB at 11 (quoting Pet. Ex. BB.2 at 3). He agreed that there was "a paucity of published data" about the association between vaccination and FM. Pet. Ex. FF at 2.

ii. Althen Prongs Two and Three

Dr. Jeret opined that Petitioner developed FM "as a result of the flu vaccination he received on September 4, 2016." Pet. Ex. BB at 13. He asserted there was a "logical sequence of cause-and-effect showing that the vaccination was the reason for the injury" based on the temporal relationship and exclusion of other causative factors. Id. at 12. He explained that there was "[n]o other cause" for the Petitioner's "dramatic change" in symptoms other than vaccination. Id. at 13. Dr. Jeret agreed that imaging studies, blood tests, cerebrospinal fluid abnormalities, and EMG criteria do not factor into the diagnosis of FM. Pet. Ex. FF at 2.

Regarding the temporal association between vaccination and onset of FM, Dr. Jeret opined that the medical records indicated that symptoms "began a week or so after vaccination." Pet. Ex. BB at 12. He opined this time frame was "consistent with the typical delay of at least several days for other vaccine-triggered autoimmune responses, e.g., GBS." Id. at 12-13.

4. Respondent's Expert, Dr. Dara G. Jamieson[85]

a. Background and Qualifications

Dr. Jamieson is a board-certified neurologist. Resp. Ex. A at 1; Resp. Ex. F at 2. She received her medical degree from the University of Pennsylvania, followed by a neurology residency and a cerebrovascular fellowship at the University of Pennsylvania Hospital. Resp. Ex. F at 1. Dr. Jamieson was a practicing neurologist for 32 years before transiting to a voluntary facility appointment. Resp. Ex. A at 1. She is currently a Clinical Associate Professor of Neurology at Weill Cornell Medicine, where she teaches medical students, residents, and

[84] Gulf War syndrome is "a group of symptoms of unknown cause, seen in military personnel of the United States and its allies in the Persian Gulf conflict of the early 1990s, consisting of widespread pain including [FM] and headaches, gastrointestinal distress, and memory disorders." Gulf War Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110690 (last visited Oct. 2, 2024).

[85] Respondent filed two expert reports from Dr. Jamieson. Resp. Exs. A, E.

fellows. Id. Dr. Jamieson has lectured extensively on multiple neurological topics. Id. She serves as an editor and reviewer for several neurology journals. Id. Dr. Jaimeson has authored or co-authored numerous neurology papers, chapters, and review articles as well as authored two books on vascular neurology. Id. at 2; Resp. Ex. F at 10-15.

b. Diagnosis Opinion

Dr. Jamieson disagreed that Petitioner has FM. Resp. Ex. A at 18. She opined that "approximately 10 months after receiving the [flu] vaccine, [Petitioner] reported back pain and stiffness, followed by diffuse pain and fatigue." Id. at 19. She described these symptoms as non-specific, noting "they do not correlate with any reproducible findings on examination or abnormalities on extensive testing." Id. She concluded that Petitioner's "subjective complaints, inconclusive physical examination, and unremarkable testing do not establish the diagnosis of [] [FM]." Id.

She explained that FM is a syndrome[86] "characterized by chronic widespread pain" and "persistent non-inflammatory musculoskeletal pain." Resp. Ex. A at 12-13. Accompanying symptoms include "fatigue, insomnia, morning stiffness, depression, anxiety, and cognitive problems." Id. at 13. Most patients with FM have a "negative affect . . . and impaired health-related quality of life." Id. Diagnosis is based on patient symptoms without objective criteria seen on physical examination or supported by diagnostic evaluation. Id. According to Dr. Jamieson, the lack of objective findings has made it difficult to reach consensus on diagnostic criteria and made it difficult to understand the "pathophysiological mechanism" of the illness. Id. After describing the difficulty reaching consensus about diagnostic criteria, Dr. Jamieson agreed that current diagnostic criteria are based on "pain in multiple regions . . . accompanied by fatigue, waking unrefreshed, and cognitive symptoms." Id.

In her second expert report, Dr. Jamieson reviewed the changing diagnostic criteria over the past three decades, noting that such changes "emphasize [] the nebulous nature" of the condition. Resp. Ex. E at 6.

c. Causation Opinion

i. Althen Prong One

Dr. Jamieson opined there was no "unifying theory of [FM] pathogenesis." Resp. Ex. A at 13. The theories "are varied and do not account for the wide array of [FM] manifestations and co-morbid conditions." Id. One hypothesis is that FM is a "disorder of pain regulation with central sensitization causing an abnormal reaction to sensory stimuli." Id. Another suggested

[86] Dr. Jamieson used the abbreviation FMS, for fibromyalgia syndrome, instead of FM, throughout her reports. For consistency, the undersigned uses the abbreviation FM in this Decision.

mechanism is that FM is "a dysautonomia[87] related neuropathic pain syndrome." Id. at 13-14. She stated "[d]espite multiple proposed yet unproven theories, the pathophysiological cause of [FM] is still unknown." Id. at 13-14. Since the pathogenesis of FM is not known, Dr. Jamieson opined that "it is not possible to speculate" about its causal mechanism relative to vaccination. Id. at 18. Moreover, Dr. Jamieson opined that FM "is not caused by vaccination, and specifically has not been associated with the flu vaccine." Id. at 14. She cited medical articles in support of this opinion.

In Cassisi et al.,[88] the authors discussed the FM symptom of chronic widespread pain. Resp. Ex. A, Tab 7 at 1. Based on a review of medical literature, the authors determined there was "no clear-cut evidence of FM or [chronic widespread pain] due to infections or vaccinations." Id. However, they reported a "higher prevalence of FM and chronic pain . . . in patients with Lyme disease, [human immunodeficiency virus], [and] [hepatitis C virus] infection." Id. Additionally, there was some suggestion that other infections may be characterized by FM and chronic pain, including infections caused by mycoplasma bacteria, hepatitis B virus, HTLV I retrovirus, and parvovirus B19. Id. The authors stated there are "[s]ome unconfirmed evidence and case reports suggest[ing] that vaccinations may trigger FM or chronic pain." Id. "However, the association, (if any) has not been established and remains obscure." Id. at 2.

Ablin et al. (published in 2015)[89] reported on a study finding the flu vaccination to be "safe and effective" in patients with FM. Resp. Ex. A, Tab 9. The study examined 19 FM patients as compared to 38 controls; all patients in both groups received the inactivated flu vaccine. Id. at 1. There were no severe post-vaccination reactions, no significant changes in the WPI or symptom severity scale, and no worsening of FM symptoms. Id. at 3.

In her second expert report, Dr. Jaimeson refuted Dr. Akbari's opinion that Petitioner's MTHFR genetic mutation supported a causal association with his flu vaccination. Resp. Ex. E at 1. Dr. Jamieson explained that the MTHRF mutation is commonplace and that there is no evidence to suggest that it leads to any "unique characteristic or vulnerability" that can increase the risk of vaccination or otherwise cause FM. Id. at 2. She cited several studies that support her opinion.

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[87] Dysautonomia is the "malfunction of the autonomic nervous system." Dysautonomia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15146 (last visited Oct. 2, 2024).

[88] Gianniantonio Cassisi et al., Chronic Widespread Pain and Fibromyalgia: Could There Be Some Relationship with Infections and Vaccinations?, 29 Clinical & Experimental Rheumatology S118 (2011).

[89] Dr. Jeret cited an earlier paper by Ablin et. al., published in 2006, in support of a possible link between vaccination and FM. See Pet. Ex. BB at 11 (citing Pet. Ex. BB.1).

Ahi et al.,[90] reported on their study of 100 FM patients compared with 100 controls to evaluate whether the MTHFR gene (C677T genotype) was associated with FM. Resp. Ex. E, Tab 2 at 1. They found that patients who had the 677 C allele of the MTHFR gene were approximately two times more likely to have FM than those with the 677 T allele.[91] Id. at 3. "That is, CC genotype carriers (normal genotype) were more prone to FM [] when compared to TT genotype carriers (homozygous mutant) of the MTHFR gene." Id. at 4. Although MTHFR C677 TT carriers were thought to be predisposed to depression, the genotype "was found to be protective against FM[] in [the] study." Id.

Khalil et al.,[92] studied 22 patients with FM and 22 healthy controls to evaluate whether the C677T polymorphism genotype, MTHFR rs1801133, along with two other possible genetic predispositions for FM, were associated with FM. Resp. Ex. E, Tab 3 at 1-2. The study did not reveal "any significant associations" between the MTHFR genotype and clinical symptoms in either group. Id. at 3-4. The authors concluded there was no association between the MTHFR genetic polymorphism "with the vulnerability of a person for the development of FM[]." Id. at 7.

Similar results were reported by Inanir et al.,[93] in a study of 200 FM patients compared with 190 controls, which showed "no statistically significant relation between MTHFR C6771 mutation and FM[]." Resp. Ex. E, Tab 4 at 1. However, the study did show that "dry eye and feeling of stiffness," clinical characteristics of FM, were "significantly related with MTHRF C677T mutation." Id.

In further support of her position that there is no basis for Dr. Akbari's opinion that a MTHFR genetic mutation can predispose one to FM, she cited a recent review article by Qureshi et al.,[94] which identified possible genetic mutations thought to increase the risk of FM. Resp.

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[90] Emine Dündar Ahi et al., Association Between Fibromyalgia Syndrome and MTHFR C677T Genotype in Turkish Patients, 4 J. Surgery & Med. 235 (2020).

[91] Alleles are "one of the two or more alternative forms of a gene that can occur at a particular chromosomal locus and that determine alternative characters in inheritance." Allele, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=1775 (last visited Oct. 28, 2024). The C677 MTHFR has two alleles (C and T) which form three observable genotypes: CC homozygous normal as well as CT heterozygote and TT homozygote mutant genotypes. See Resp. Ex. E, Tab 2 at 2. Petitioner's laboratory results show he is heterozygous for MTHFR C677T. Pet. Ex. E at 10.

[92] Raida Khalil et al., Investigation of ACE rs4646994, MTHFR rs1801133 and VDR rs2228570 Genotypes in Jordanian Patients with Fibromyalgia Syndrome, 21 Endocrine Metabolic & Immune Disorders 1920 (2021).

[93] Ahmet Inanir et al., Angiotensin Converting Enzyme and Methylenetetrahydrofolate Reductase Gene Variations in Fibromyalgia Syndrome, 564 Gene 188 (2015).

[94] Aniqa G. Qureshi et al., Diagnostic Challenges and Management of Fibromyalgia, 13 Cureus e18692 (2021).

Ex. E at 3 (citing Resp. Ex. E, Tab 5). In the Qureshi et al. article, the MTHFR gene variant was not identified as a mutation that increased the risk of FM. See Resp. Ex. E, Tab 5 at 9.

Based on the medical literature, Dr. Jamieson concluded that it was "not reasonable for Dr. Akbari to assume that the presence of common genetic mutations is proof of vaccine-related vulnerability" in FM. Resp. Ex. E at 3. Instead, she opined that FM is a "syndrome of unclear and multifactorial pathophysiological mechanisms." Id. Dr. Jamieson further opined "[t]here is no pathophysiological or epidemiological nexus between a common gene mutation and a diverse collection of symptoms of unclear etiology." Id.

Next, Dr. Jamieson disagreed with Dr. Akbari's assertion that Petitioner's positive EBV test was relevant or that the paper by Buchwald et al.[95] supported any association between EBV infection and FM. Resp. Ex. E at 3-4. Buchwald et al. noted that the clinical features of FM shared some similarities with reactivated latent EBV infection, including "fatigue, myalgias, and arthralgias." Pet. Ex. DD.35 at 1, 4. The authors studied the common characteristics of the two conditions. Id. at 1-2. Although the study confirmed that FM and EBV patients shared some common symptoms, the EBV serology results did not significantly differ between the 50 FM patients and those in the control groups. Id. at 5. Moreover, "there was no evidence that reactivation of latent EBV infection was associated with the patients' illness." Id. Dr. Jamieson reiterated that the paper did not "find any association between EBV infection and [FM]." Resp. Ex. E at 4.

In her second expert report, Dr. Jamieson also provided supportive medical literature stating there was "no established connection between [the] [flu] vaccination and [FM]." Resp. Ex. E at 6 (citing Pet. Ex. BB.1 at 5 ("[T]he possible relationship of . . . [FM] with vaccination [] remains to be established."); Pet. Ex. BB.2 at 3 ("The role of vaccination in precipitating [FM] . . . remains to be established.").

ii. Althen Prong Two and Three

Regarding her opinions about whether there was a logical sequence of cause and effect, Dr. Jamieson described Petitioner's clinical course, noting that after his flu vaccination, he sought medical care "multiple times," complaining of upper respiratory problems and general complaints, all unrelated to his flu vaccine. Resp. Ex. A at 11. At visits on December 21, 2016 and April 18, 2017, Petitioner did not report FM symptoms related to his prior flu vaccination. Id. His symptom of back stiffness was first documented by his chiropractor on June 24, 2017, and the reference did not mention the flu vaccination. Id. It was not until July 20, 2017 that Dr. Thompson documented that Petitioner related his symptoms back to one week after vaccination. Id.

In addition to the fact that Petitioner's symptoms were not documented until July 2017, Dr. Jamieson opined there was "no consistent or reproducible abnormality correlating with these complaints [] found on [] multiple physical examinations by multiple primary care practitioners

[95] Dedra Buchwald et al., The "Chronic, Active Epstein-Barr Virus Infection" Syndrome and Primary Fibromyalgia, 30 Arthritis & Rheumatism (1987).

and specialists." Resp. Ex. A at 11-12. Diagnostic testing, including blood work, brain and spine imaging, and EMG/NCV, did not reveal an underlying diagnosis. Id. at 12. Petitioner was referred to specialists in rheumatology, neurology, and otolaryngology, and these specialists did not reach a specific diagnosis or suggest that the flu vaccination was associated with Petitioner's symptoms. Id. Neither the rheumatologist or neurologist attributed Petitioner symptoms to FM or the flu vaccine. Id.

Dr. Jamieson concluded that the symptoms Petitioner reported ten months after vaccination "do not support a chronological link between [his] subjective complaints and his [flu] vaccination." Resp. Ex. A at 18. She found "[it] [was] not credible that [Petitioner] had significant symptoms immediately after his vaccination and yet [] did not relay his concerns to multiple healthcare providers at multiple visits in the months after his vaccination." Id. Because Petitioner failed to seek medical help specifically for these "supposedly disabling symptoms of months duration is implausible given multiple intervening medical visits to report milder symptoms of shorter duration." Id. And "[e]ven if [Petitioner's] complaints were to be believed as originating soon after his vaccination, the mere determination that they occurred after the vaccination does not establish that they were triggered or caused by the vaccination. Subsequent occurrence does not establish causation." Id.

Further, Dr. Jamieson suggested there were other causes for Petitioner's nonspecific complaints, including "degenerative disease of the lumbar spine, obesity, obstructive sleep apnea, vitamin (folate) deficiency, and low testosterone." Resp. Ex. A at 18.

As for prong three, Dr. Jamieson opined that Petitioner did not have the onset of FM "within any time period" that would link it to his flu vaccination. Resp. Ex. E at 5.

In conclusion, Dr. Jamieson opined that, "more likely than not, there is no causative, triggering, or contributing association between [Petitioner's] vaccination and his complaints." Resp. Ex. E at 7.

5. Respondent's Expert, Dr. Rolad Staud[96]

a. Background and Qualifications

Dr. Staud is a board-certified rheumatologist and Professor of Medicine at the University of Florida. Resp. Ex. C at 1; Resp. Ex. G at 1. He received his medical degree from Freie Universität Berlin in 1972, followed by an internal medicine residency in Germany and in New Jersey at Englewood Hospital. Resp. Ex. G at 1. Thereafter, Dr. Staud completed a fellowship in rheumatology at New York University. Id. Dr. Staud is regularly involved in the care of patients with rheumatological conditions and chronic musculoskeletal conditions including FM. Resp. Ex. C at 1. His specialty is the field of chronic musculoskeletal conditions. Id. Dr. Staud directs a clinical program in this specialty. Id. He teaches and supervises medical residents and fellows in clinical rheumatology. Id. Dr. Staud is the director of the Center for Chronic Musculoskeletal Pain and Fatigue Research at the University of Florida. Id. He conducts NIH-

[96] Respondent filed two expert reports from Dr. Staud. Resp. Exs. C-D.

funded research on the mechanisms of chronic musculoskeletal pain and fatigue. Id. Dr. Staud has published extensively on chronic musculoskeletal pain, chronic fatigue, and functional neuro-imaging of patients with chronic musculoskeletal pain (FM) and chronic fatigue as well as co-authored textbooks and books on these subjects. Id.; Resp. Ex. G at 3-26.

b. Diagnosis Opinion

Dr. Staud agreed with other experts that FM is a "chronic musculoskeletal disorder of widespread pain" that is diagnosed using ACR criteria published in 1990 and revised in 2011. Resp. Ex. C at 4. The ACR diagnosis criteria include "widespread pain, [] tender points, and [] poor sleep, fatigue, and memory problems." Id. According to Dr. Staud, Petitioner did not meet these criteria. Resp. Ex. D at 3. He also criticized Dr. Jeret's retrospective application of the criteria, stating that it violated the parameters stated within the criteria. Id.

Dr. Staud reviewed Petitioner's medical records and the petition. Resp. Ex. C at 1-3. Reviewing the petition, Dr. Staud noted that Petitioner alleged that he developed back pain three days after vaccination, which later spread to additional body sites. Id. After several months of unexplained musculoskeletal pain, Petitioner was ultimately diagnosed with FM. Id. Based on the records, on July 20, 2017, Petitioner saw Dr. Thompson, whose physical examination "noted symmetrical trigger points over classic [FM] sites," and Petitioner was diagnosed with "[FM], obstructive sleep apnea [], and fatigue." Id. at 2. While Dr. Staud acknowledged that Petitioner was diagnosed with FM by his treating physician, Dr. Thompson, Dr. Staud noted that about one month later, on August 10, 2017, Petitioner was seen by a rheumatologist, Dr. Harwell, who "excluded the diagnosis of [FM]." Id.

Although Dr. Harwell did not find that Petitioner had FM, in May of 2019, Petitioner saw Dr. Chothmunethink who documented that Petitioner had "[FM], obstructive sleep apnea, hypertension, and chronic [EBV] infection." Resp. Ex. C at 3 (citing Pet. Ex. G at 1-8). Thus, Dr. Staud acknowledged that Petitioner's treating physicians diagnosed FM.

Dr. Staud disagreed with Dr. Jeret that Petitioner met the ACR 1990 or 2011 diagnostic criteria for FM. Resp. Ex. D at 3. He agreed with Dr. Jeret that the 1990 criteria required "chronic widespread pain for at least [three] months" and "the presence of at least 11 out of 18 tender points." Id. However, Dr. Staud opined that in Petitioner's case, the presence of widespread musculoskeletal pain or requisite tender points were never established, and therefore, the 1990 criteria were not met. Id.

Regarding the 2011 criteria, Dr. Staud opined that Petitioner did not meet the criteria because Dr. Jeret's assessment did not reflect a period of "one week" prior to the examination.[97] Resp. Ex. D at 3. Dr. Jeret's retrospective application of the criteria "over a prolonged period of time (more than [one] week) . . . is inappropriate to support the diagnosis of FM." Id. at 3. According to Dr. Staud, this approach results in "label[ing] [a] patient with unexplained somatic

[97] The ACR 2011 Criteria WPI questionnaire and Symptom Severity Score questionnaire rely on a period of one week prior to evaluation to generate a diagnostic score. Pet. Ex. BB.17 at 9.

symptoms as FM, without rigorously applying the validated clinical or research criteria of this illness." Id.

In addition to disagreeing with Dr. Jeret's retrospective application of the criteria, Dr. Staud also explained that many health care providers fail to rigorously apply the various diagnostic criteria of FM which has caused widespread overdiagnosis as well as underdiagnosis of FM. Resp. Ex. D at 3. In a 2019 study by Wolfe et al.,[98] comparisons were made between how patients completed questionnaires using the ACR 2010 preliminary diagnostic criteria and the 2011 modified criteria, and patients with a clinical diagnosis based on International Classification of Diseases, Tenth Revision ("ICD-10")[99] codes for FM. Resp. Ex. D, Tab 3 at 1. "Physicians failed to identify 60 criteria-positive patients (49.6%) and incorrectly identified 43 criteria-negative patients (11.4%)." Id. at 4. Of 104 patients clinically diagnosed with FM, "only 61 (58.7%) actually satisfied [the ACR] criteria, and among the 393 not diagnosed with [FM] by clinicians, 60 (15.3%) satisfied the 2011 criteria." Id. The authors noted their findings are supported by a 2016 study by Walitt et al.,[100] which showed "the self reported diagnosis of [FM] is likely to be wrong" and also found overdiagnosis and underdiagnosis of FM among patients. Id. at 6-7.

c. Causation Opinion

i. Althen Prong One

Regarding the cause of FM, Dr. Staud explained that observational studies have suggested an association between FM and infection, trauma, and motor vehicle accidents, but supportive data are weak or non-existent. Resp. Ex. C at 4. As for vaccination, he opined that no "reliable scientific evidence" supports an association. Id.

Dr. Staud stated that Petitioner advanced a theory of causation based on reactivation of EBV infection, but he disagreed that there is any "convincing evidence" to support this theory. Resp. Ex. C at 4-5. Further, he stated that there is "very little reliable evidence in the literature

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[98] Frederick Wolfe et al., Diagnosis of Fibromyalgia: Disagreement Between Fibromyalgia Criteria and Clinician-Based Fibromyalgia Diagnosis in a University Clinic, 71 Arthritis Care & Rsch. 343 (2019).

[99] The ICD-10 codes are a standardized system used to code diseases, morbidity, and cause of death data. See Classification of Disease, Functioning, And Disability, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchs/icd/icd-10-cm/index.html (last visited October 22, 2024). FM is coded as M79.7, classifying it as an "unspecified soft tissue disorder[]," but does provide any criteria for diagnosis. See National Center for Health Statistics – ICD-10-CM, Ctrs. for Disease Control & Prevention, https://icd10cmtool.cdc.gov/?fy=FY2025&query=m79.7 (last visited October 22, 2024).

[100] Brian Walitt et al., Three-Quarters of Persons in the US Population Reporting a Clinical Diagnosis of Fibromyalgia Do Not Satisfy Fibromyalgia Criteria: The 2012 National Health Interview Survey, 11 PloS One e0157235 (2016).

related to possible causation of FM with attenuated vaccines, like the [] [f]lu-vaccine." Id. at 5. Since the flu vaccine was not a "live-virus vaccine, direct infection of tissues with [flu] virus is not possible." Resp. Ex. D at 2.

ii. Althen Prongs Two and Three

Dr. Staud opined that "the evidence is insufficient to conclude that [Petitioner] more likely than not, suffered any injury, specifically FM, [or] EBV reactivation . . . as a consequence of the [flu] vaccination" administered on September 4, 2016. Resp. Ex. C at 5.

Regarding Petitioner's theory of causation based on EBV reactivation, Dr. Staud opined that Petitioner's EBV IgM titers were negative. Resp. Ex. C at 4 (citing Pet. Ex. F at 48). Therefore, Petitioner did not have antibody titers that supported this EBV reactivation theory. Id. Direct infection is also not a reasonable theory because Petitioner did not receive a live virus vaccine but an attenuated vaccine. Resp. Ex. D at 2.

Next, Petitioner reported his onset of pain was three days after vaccination, "which is too long for an unspecific effect [of vaccination] and too short for an adverse response from the specific immune system." Resp. Ex. C at 5. Dr. Staud opined that "this rapid onset of pain symptoms is more consistent with myofascial pain [], most often due to chronic arthritis of the joints and spine." Id.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321

(quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (noting it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993); Doe/70 v. Sec'y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010) ("Given the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law."); Rickett v. Sec'y of Health & Hum. Servs., 468 F. App'x 952 (Fed. Cir. 2011)

(non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), vacated on other grounds, 809 F. App'x 843 (Fed. Cir. 2020); Cucuras v. Sec'y of Health & Hum. Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. Cucuras, 993 F.2d at 1528; see also Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." (citing United States v. U.S. Gypsum Co., 333 U.S. 364, 396 (1947))), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege he suffered a Table Injury, he must prove a vaccine he received actually caused his injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. DIAGNOSIS AND ONSET

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury [,]" determining facts relating to the claimed injury can be significant. Id. Here, both diagnosis and the factual issue of onset are in dispute.

A. Diagnosis

The undersigned finds that there is preponderant evidence to support Petitioner's diagnosis of FM, as explained below.

The ACR 2010 and 2011 diagnostic criteria establish that widespread pain and fatigue are required for a diagnosis of FM. On July 20, 2017, Dr. Thompson's records reflect that Petitioner complained of "pain all over his body" and an inability to exercise. Pet. Ex. C at 8. Dr. Thompson assessed Petitioner with fatigue and FM. Therefore, on July 20, 2017, the Petitioner's

medical records verify the presence of pain all over the body, an assessment of fatigue, and diagnosis of FM.

Dr. Hagenau opined that Petitioner's generalized pain and fatigue were caused by his FM. Dr. Jeret agreed that Dr. Thompson's diagnosis of FM on July 20, 2017 was appropriate based on a retrospective analysis of the medical records. Dr. Jamieson does not dispute that Petitioner had complaints of diffuse pain and fatigue approximately 10 months after vaccination. Dr. Staud does not agree that Petitioner ever met the criteria for a diagnosis of FM.

Based on the entries in Petitioner's medical record on July 20, 2017, noting pain all over his body, fatigue, and Dr. Thompson's diagnosis of FM, the undersigned finds there is preponderant evidence to support the diagnosis of FM as of that date. Further, Petitioner continues to have a diagnosis of FM and has been treated for the condition since 2017. This finding does not rely on a technical application of the ACR criteria. The criteria specifically require that the pain be present for a period of three months and that aspect of the criteria is not established on July 20, 2017, as it is the first documentation of widespread pain and fatigue. The undersigned also acknowledges the problem with Dr. Jeret's retrospective application of the criteria, in that it was not applied for the period of one week, like it would have been if the assessment was made in real time when the Petitioner presented in 2017. Instead of requiring strict adherence to the ACR criteria, the undersigned places significant weight on the July 20, 2017 FM diagnosis by Petitioner's treating physician, Dr. Thompson.

B. Onset

Regarding onset, the undersigned finds there is preponderant evidence that the onset of Petitioner's FM was approximately July 20, 2017, but not before that date. Contemporaneous medical records from four different health care providers do not document complaints of widespread pain or fatigue after Petitioner's flu vaccination. The first documentation of these complaints did not occur until July 20, 2017, by Dr. Thompson.

The first medical visit after vaccination was November 18, 2016, when Petitioner saw Dr. Tissot with complaints of hematuria and flank pain and was diagnosed with kidney stones. Pet. Ex. MM at 23-25. Dr. Tissot did not document fever, tiredness, back pain, neck pain, or numbness, or any other complaints referable to Petitioner's flu vaccination.

Next, Petitioner saw Nurse Practitioner Jones at The Little Clinic on December 7, 2016 for an upper respiratory infection. Petitioner reported ear pain for one week and rated his pain as 6/10. Pet. Ex. B at 6. At the hearing, Petitioner testified that the pain score of 6 related to back pain from the flu vaccination, but there is no reference to back pain during the visit record, only ear pain. See Tr. 16. Further, at this visit, Petitioner's receipt of the seasonal flu vaccination was documented but no adverse effects were noted. Pet. Ex. B at 6.

On April 18, 2017, Petitioner returned to The Little Clinic, and saw Nurse Practitioner Johnson, with complaints of seasonal allergies. Pet. Ex. B at 4. Petitioner did not report pain, and his pain scale was documented as zero (0/10). Id.

The fourth time Petitioner saw a health care provider after vaccination was on June 13, 2017, when he saw Dr. Thompson for his annual physical examination. At this visit, Petitioner complained that his insurance did not cover some of his lab studies. Dr. Thompson documented Petitioner's concerns about the insurance issue. Records from this visit include a review of systems and physical examination. Review of systems did not reflect any pain and Petitioner had a normal physical examination with no complaints of costochondral tenderness, back or spine pain, or any other complaints of pain. Musculoskeletal and neurological examinations were normal. Sensory examination was also normal. See Pet. Ex. C at 13-15.

In summary, after his flu vaccination, Petitioner was seen by four different health care providers. These four providers took a history from Petitioner and documented his complaints at each visit. None of these providers documented any back pain, body aches, fatigue, or any other adverse effect related to Petitioner's flu vaccination. But they did document specific conversations about the lack of insurance coverage for specific lab tests. Therefore, the undersigned finds that Petitioner did not have widespread body aches or pain, back pain, or fatigue, or other indices of FM during this time frame.

Medical records generally "warrant consideration as trustworthy evidence." Cucuras, 993 F.2d at 1528. However, greater weight is typically given to contemporaneous records. Vergara v. Sec'y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."). The weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Cucuras, 993 F.2d at 1528. Here, the earlier-in-time records are silent regarding any signs or symptoms which were later attributed to FM. The fact that the records were documented by four different health care providers adds support for the undersigned's finding that they are reliable.

Several years after vaccination, and in support of his allegations in this claim, Petitioner filed two affidavits from Dr. Thompson, one in 2019 and the other in 2020, averring that Petitioner experienced a sudden onset of back pain within days or a week of his flu vaccination. Dr. Thompson's affidavits were created more than three years after the facts at issue. Further, in the affidavits, Dr. Thompson described Petitioner's complaints of pain as occurring within days or one week of vaccination. However, Dr. Thompson did not see Petitioner in the days or week after vaccination. Based on the contemporaneous medical records, Dr. Thompson did not see Petitioner until June 13, 2017, six months after vaccination. Therefore, it does not appear that Dr. Thompson had personal knowledge or information upon which to base his testimony.

For these reasons, the undersigned finds Dr. Thompson's affidavits do not provide persuasive evidence. See Zumwalt v. Sec'y of Health & Hum. Servs., No. 16-994V, 2019 WL 1953739, at *19 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (rejecting opinion from a treating provider when he presented an opinion two-and-one-half years after treatment and after litigation was initiated), mot. for review den'd, 146 Fed. Cl. 525 (2019); Vergara, 2014 WL 2795491, at *4

("[T]estimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." (quoting Murphy, 23 Cl. Ct. at 733)).

The undersigned finds the letter by Dr. Gore lacks persuasive value for similar reasons. Dr. Gore's letter is dated August 27, 2020, four years after the events at issue. He did not begin treating Petitioner until March 2020. Therefore, Dr. Gore has no personal knowledge or information of the events. Further, in his letter, Dr. Gore offers no opinions or information, but simply states that he agrees with the letter written by Dr. Thompson. Dr. Gore offers no independent information or opinions. Thus, the undersigned affords little probative value to this document.

In the undersigned's experience of reviewing medical records in the context of vaccine-alleged injuries, and adjudicating these claims, Petitioners who have pain may delay seeking care, but when they do see a medical provider, they report their symptoms, especially when their symptoms are significant, like those described here. Although Petitioner testified that he reported his complaints relative to FM, four different medical providers failed to document them. This conclusion is difficult to accept, especially since one of those visits was for an annual physical examination that included a review of systems and physical examination.

Additionally, in his affidavits and testimony, Petitioner failed to recall or mention his medical visits for kidney stones. This is particularly important since kidney stones are known to cause severe pain.[101] In fact, on July 20, 2017, Petitioner saw Dr. Tissot for kidney stones. And X-rays were abnormal, showing lumbar facet sclerosis with bony bridging. Petitioner did not reference these facts in his affidavits or testimony. His failure to recall or note other important medical events that occurred during the same time as his pain which he attributes to FM suggests that his memory about the chronology of events may have waned over time.

The same problems exist with the other affidavits and testimony in this matter. The statements or testimony is inconsistent with the contemporaneous medical records. Further, much of what the lay witnesses recall is based on what Petitioner told them, and as explained above, it is not clear whether Petitioner accurately remembers the chronology of events.

Because Petitioner's affidavit and testimony are inconsistent with and contradicted by the contemporaneous medical records, it is reasonable to give greater weight to the contemporaneous medical records. See Cucuras, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); Doe/70, 95 Fed. Cl. at 608; Stevens v. Sec'y of Health & Hum. Servs., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that "clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"); Vergara, 2014 WL 2795491, at *4. This finding also extends to the lay witness affidavits and testimony. Other

[101] Kidney stones in the bladder may cause pain in the lower abdomen while stones in the ureter, renal pelvis, or "or any of the kidney's drainage tubes may cause back pain or renal colic. Renal colic is characterized by an excruciating intermittent pain." Stones in the Urinary Tract, Merck Manual, https://www.merckmanuals.com/home/kidney-and-urinary-tract-disorders/stones-in-the-urinary-tract/stones-in-the-urinary-tract (last visited Oct. 21, 2024).

special masters have been faced with similar situations and found the contemporaneous medical records more persuasive than the affidavits and testimonies of lay witnesses. See, e.g., Rote v. Sec'y of Health & Hum. Servs., No. 90-036V, 1992 WL 165970, *5 (Cl. Ct. Spec. Mstr. July 1, 1992) (finding the lay witness testimony insufficient to overcome the weight of the contemporaneous medical records); Bergman v. Sec'y of Health & Hum. Servs., No. 90-1252V, 1992 WL 78671, *4 (Cl. Ct. Spec. Mstr. Mar. 31, 1992) (same); Daiza v. Sec'y of Health & Hum. Servs., No. 90-1188V, 1992 WL 59709, *4 (Cl. Ct. Spec. Mstr. Mar. 5, 1992) (same).

For the above reasons, the undersigned finds that preponderant evidence places the onset of Petitioner's symptoms of FM approximately July 20, 2017, as documented in Dr. Thompson's records of that visit.

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds Petitioner, through his three experts, Dr. Hagenau, Dr. Jeret, and Dr. Akbari, failed to provide preponderant evidence of a sound and reliable theory to explain how the flu vaccination can cause FM. There are several reasons for this finding.

As explained by Dr. Hagenau, the current thinking is that "the primary problem in [FM] is dysfunction in the central pain pathways in the brain and spinal cord. Those nerve pathways become hyperactive, hypersensitive, generating the experience of pain, tingling[,] or burning in areas of the body where there can be found nothing wrong peripherally." Pet. Ex. R at 5. He adds that the "interaction between the central neurons and the peripheral neurons is not well understood." Id.

Thus, how the dysfunction in the central pathways of the brain and spinal cord occurs to cause FM is not known. The lack of knowledge about the cause of FM is confirmed in the medical literature. See, e.g., Pet. Ex. BB.1 at 1 ("[FM] continues to raise debate[,] . . . [and] the etiology of [FM] is yet unclear."); Pet. Ex. BB.2 at 3 ("The role of vaccination in precipitating

[FM] and related syndromes still remains to be established."); Pet. Ex. DD.29 at 1 (noting "the pathogenesis of FM is not fully understood, especially because compared to neuropathic conditions, in FM the source of sensory inputs is unknown").

Dr. Hagenau's causal theory is that vaccinations "induce an inflammatory response." Pet. Ex. R at 5. This response plus a prior "documented [flu] infection" "resulted in activation of the nervous system and immune system that was long lasting and self-perpetuating" causing FM. Id. However, Dr. Hagenau does not explain how the flu vaccine causes an inflammatory response, why any preceding infection is relevant, or how the inflammatory response triggered a long lasting and self-perpetuating chronic condition.

Petitioner acknowledged that Dr. Hagenau's expert report had limitations because it did not reference medical literature or address onset, and Petitioner agreed that it "may not fully meet the standard of preponderance of the evidence due to the omissions." Pet. Submission at 18.

The undersigned agrees, and finds that here, Dr. Hagenau's theory of causation is unsupported by medical or scientific facts, research, or any other reliable evidence. Moreover, his theory is speculative and/or conclusory in nature. When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. den'd, decision aff'd, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. Id.

The next theory, molecular mimicry, is inconsistent with Dr. Hagenau's theory. Instead of an inflammatory response, Dr. Jeret offers the theory of molecular mimicry, an "autoimmune response," to explain how the flu vaccination causes FM. Pet. Ex. BB at 11. He explains this "same immune error" is the mechanism responsible for GBS after flu vaccination. Id. The medical literature, however, does not show that FM is an autoimmune illness. See, e.g., Pet. Ex. BB.2 at 1-2 ("[FM] cannot be considered an autoimmune disease . . . .").

Moreover, Dr. Jeret did not offer evidence in support for the theory of molecular mimicry. He did not explain what antigen or protein in the vaccine shares homology with the human body so to implicate molecular mimicry. And he did not offer any evidence that molecular mimicry has been recognized or accepted as a potential mechanism for vaccine-related FM. Instead, he asserts that FM is like GBS, and that because molecular mimicry is posited as the causal mechanism of vaccine-induced GBS, it is the relevant mechanism here. But GBS is a demyelinating condition, and there is no evidence to show that FM is a demyelinating condition. Dr. Jeret did not show that FM and GBS are similar conditions, or that FM was a demyelinating injury like GBS.

Therefore, Dr. Jeret has not explained the relevance of molecular mimicry, or his comparison between FM and GBS, or his references to articles about GBS. A theory relevant to one vaccine-related illness cannot automatically be imputed to a different illness, particularly when the illnesses lack the same etiology. "An expert may 'extrapolate from existing data,' and use 'circumstantial evidence,' [b]ut the reasons for the extrapolation should be transparent and persuasive." K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *12 (Fed. Cl. Spec. Mstr. July 7, 2016) (internal citations omitted) (first quoting Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 743 (2009); and then quoting Althen, 418 F.3d at 1280).

Moreover, simply offering the theory of molecular mimicry does not advance Petitioner's burden of proof where the theory has not been shown to be relevant to the disease at issue. The medical literature filed here does not establish FM as an autoimmune illness, nor does it show that molecular mimicry is an accepted causal mechanism in FM. Although molecular mimicry is an accepted scientific mechanism, generally opining that molecular mimicry is a causal theory, without more, is insufficient. See, e.g., Loyd ex rel. v. Sec'y of Health & Hum. Servs., No. 16-811V, 2021 WL 2708941, at *31 (Fed. Cl. Spec. Mstr. May 20, 2021) ("[T]hough molecular mimicry is a generally accepted scientific concept, and is frequently invoked in Program cases, the mere mention of it does not constitute satisfaction of the preponderant evidentiary standard. Rather, it must be shown that the mechanism likely does link the vaccine in question to the relevant injury." (internal citations omitted)); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (explaining that "merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question" (emphasis omitted)); Sheets v. Sec'y of Health & Hum. Servs., No. 16-1173V, 2019 WL 2296212, at *17 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (determining Petitioner had not satisfied Althen prong one when he did not relate molecular mimicry "to either the vaccines in question or Petitioner's own specific condition").

Petitioner's third expert, who specializes in immunology, Dr. Akbari, also fails to offer preponderant evidence of causation for three reasons: (1) his proffered ideas about causation lack development, (2) he suggests the adoption of legal standard other than preponderant evidence, and (3) he mischaracterizes the findings of medical articles.

Dr. Akbari offers a treatise of possible immunological concepts, drawn from various clinic studies, but these ideas are not developed, and all fall short of explaining how the flu vaccine can cause FM. He discusses cytokines, chemokines, and inflammasomes and their roles in causing inflammation. But he does not address basic questions. For example, he explains that certain cytokines "could contribute to the inflammatory response in the [CNS]." Pet. Ex. DD at 5. But he does not explain what cytokines are triggered by the flu vaccination, or what part of the CNS these cytokines act upon, or how cytokines act upon the CNS. Nor does Dr. Akbari explain how the action of these cytokines induce pain or how that pain becomes widespread or chronic.

Another example is seen in his statement that the "pain in [FM] involves neuroinflammatory processes triggered by mast cells and microglia." Pet. Ex. DD at 6. Here, Dr. Akbari does not describe what he means by neuroinflammatory processes or define the terms

mast cells or microglia. Nor does he explain the role of the flu vaccine in relation to mast cells or microglia.

The lack of a causal framework is not surprising in the context of FM, where the medical literature establishes that the cause is not known. This void of knowledge, however, cannot be filled by ideas culled from clinical studies where further study is recommended, or where findings are inconclusive or inconsistent with prior studies, especially when the ideas have not been embraced by the medical community as causal mechanisms. Dr. Ackbari acknowledges that "more than a decade ago the Institute of Medicine expressed very wise and cautious language and reiterated that based on insufficient information they cannot confirm or deny any association between the flu vaccine and [FM]." Pet. Ex. DD at 23. He also describes the difficulties of showing causation in a condition like FM, where there are no "specific biomarkers, genetic testing, or lab testing to predict or assess adverse effects." Id. In the context of rare conditions with no available diagnostic tests, he suggests that "[t]he generation of hypothesis frequently is described as a creative process [] based on existing scientific knowledge, literature, intuition, and experience." Id. at 24. While a hypothesis derived from the creative process may be appropriate in a clinical animal study, the objective here is to determine whether a vaccine has caused an injury to a human being that is compensable under the Vaccine Act. As such, the creative process must give way to the legal question of whether the causal hypothesis is developed to the point that it "sound and reliable" and established by preponderant evidence.

Another reason that Dr. Akbari's opinions are not persuasive is that he seeks the adoption of a different standard than preponderant evidence. He states that "although current data are insufficient [] to establish a definitive relationship between flu vaccination and [FM], it appears clear that this vaccine is capable of causing acute FM including musculoskeletal symptoms and certainly the frequency and induction of FM cannot be ruled out after flu vaccination." Pet. Ex. DD. at 21. Here Dr. Akbari recommends a rule out standard where if vaccine causation cannot be ruled out, then compensation under the Vaccine Act should be granted. As stated in Petitioner's Prehearing Submission, Dr. Akbari "believes that the possibility of FM induction following [flu] vaccination should not be ruled out." Pet. Submission at 27.

Causation, however, must be established by a preponderance of the evidence, and a possible theory or mechanism is insufficient to establish causation by a preponderance of the evidence. See Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman, 123 Fed. Cl. at 573-74 (denying petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard); de Bazan, 539 F.3d at 1315. The fact that vaccine causation has not been ruled out is like a standard based on possibility, not probability.

Lastly, Dr. Akbari mischaracterizes the medical literature which casts doubt on his opinions and renders them less persuasive. For example, Dr. Akbari asserts that in some patients, "Th17 induced by [the] flu vaccine is capable of inducing FM." Pet. Ex. DD at 13. He cites two studies. The first one, by Bermejo-Martin et al., does not discuss the flu vaccination, only the H1N1 flu infection. See Pet. Ex. DD.23. Dr. Akbari does not acknowledge that the paper does not discuss vaccination and he does not explain how an attenuated flu vaccine is like

a live virus infection. The second article is by Lin et al., and it does not discuss how the flu vaccine can cause FM. See Pet. Ex. DD.24 at 1. Instead, the study discusses the role of Th17 in vaccine-induced immunity. Id. Dr. Akbari misrepresents the substance of both articles.

Another example is Dr. Akbari's reliance on the study by Falsetti et al. Describing the study, Dr. Akbari notes that "[s]trikingly, six patients with [FM] reported a vaccination before the onset of disease (four with [flu] vaccination)." Pet. Ex. DD at 20. However, the article actually states that "six PMR patients reported a vaccination before the onset of disease." Pet. Ex. DD.25 at 3. In his expert report, Dr. Akbari changed PMR to FM and, in doing so, materially misrepresents the findings that he cited.

Special masters must consider the credibility of expert witnesses. Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1250 (Fed. Cir. 2011). Experts who use "dubious tactics" such as mischaracterizing and misstating medical literature "profoundly undermine [their] credibility." Prokopeas, 2019 WL 2509626, at *19; see also Orm v. Sec'y of Health & Hum. Servs., No. 14-257V, 2023 WL 2984794, at *31-32 (Fed. Cl. Spec. Mstr. Apr. 18, 2023); Burgess v. Sec'y of Health & Hum. Servs., No. 17-688V, 2022 WL 17410582, at *30-31 (Fed. Cl. Spec. Mstr. Nov. 7, 2022); Rogero v. Sec'y of Health & Hum. Servs., No. 11-770V, 2017 WL 4277580, at *49-50 (Fed. Cl. Spec. Mstr. Sept. 1, 2017), aff'd, 748 F. App'x 996 (Fed. Cir. 2018).

Lastly, there are several other Vaccine Program cases with reasoned decisions regarding FM and these have not found petitioners entitled to compensation.[102] Although decisions of other special masters are not binding, the undersigned generally agrees with the reasoning of her colleagues in these cases. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

In Ruzicka, the special master denied entitlement where the petitioner alleged that the tetanus, diphtheria and pertussis ("Tdap") vaccination caused FM. Ruzicka v. Sec'y of Health & Hum. Servs., No. 17-109V, 2023 WL 8352496, at *1 (Fed. Cl. Spec. Mstr. Nov. 13, 2023). The special master noted that "FM is generally not considered to be an autoimmune disease, and thus unlikely to result from vaccination." Id. at *22. In Balasco and Fankhauser, the special master denied entitlement where the petitioner alleged the human papillomavirus ("HPV") vaccine caused FM. Balasco v. Sec'y of Health & Hum. Servs., No. 17-215V, 2020 WL 1240917, at *1 (Fed. Cl. Spec. Mstr. Feb. 14, 2020); Fankhauser v. Sec'y of Health & Hum. Servs., No. 09-590V, 2014 WL 7015509, at *1 (Fed. Cl. Spec. Mstr. Nov. 24, 2014) (same). While in Cowart and Moody, the special master found that petitioner did not establish FM was caused by the meningococcal vaccine. Cowart v. Sec'y of Health & Hum. Servs., No. 16-513V, 2021 WL

[102] In Petitioner's supplemental prehearing submission, Petitioner references flu related FM cases that have been resolved through joint stipulations or settlements. See Pet. Suppl. Submission at 2. Cases resolved by settlement are not persuasive case law as they do not contain any reasoned judicial analysis or foundational basis for opinions or rulings. See Caves v. Sec'y of Health & Hum. Servs., No. 07-443V, 2010 WL 5557542, at *17 (Fed. Cl. Nov. 29, 2010) (noting settlements cannot be used to establish entitlement for similarly situated petitioners in future cases). Therefore, these cases do not inform the undersigned's decision making.

253977, at *1 (Fed. Cl. Spec. Mstr. Jan. 5, 2021); Moody v. Sec'y of Health & Hum. Servs., No. 16-513V, 2020 WL 3264272 (Fed. Cl. Spec May 20, 2020). In Doe/70, Doe/71, and Lee, the special master denied entitlement where the petitioner alleged FM was caused by the hepatitis b ("Hep B") vaccine. Doe/70 v. Sec'y of Health & Hum. Servs., No. V, 2011 WL 539133, at *1 (Fed. Cl. Spec. Mstr. Feb. 9, 2011); Doe/71 v. Sec'y of Health & Hum. Servs., No. V, 2010 WL 2545721 (Fed. Cl. Spec. Mstr. May 26, 2010), mot. for rev. den'd, decision aff'd, 95 Fed. Cl. 598 (2010); Lee v. Sec'y of Health & Hum. Servs., No. 03-2479V, 2005 WL 1125672, at *1 (Fed. Cl. Spec. Mstr. Apr. 8, 2005).

In his supplemental prehearing submission, Petitioner acknowledges that compensation has been denied in prior cases where petitioners claimed that FM resulted from a different vaccine. Petitioner argues that these prior cases "faced distinct shortcomings absent in the present records." Petitioner's Prehearing Submission Supplement ("Pet. Suppl. Submission"), filed Oct. 12, 2023 (ECF No. 99-1) at 4. While the cases described above may have had different shortcomings, the current case has its own deficiencies that preclude compensation, as discussed above. On the whole, all of these cases illustrate the point that FM has not been shown by preponderant evidence to be a vaccine-related illness.

In summary, Petitioner has failed to offer a sound and reliable medical theory in support of his claim. Thus, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the first Althen prong.

B. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528 (Fed. Cir. 1993). While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court").

Since Petitioner failed to prove Althen prong one, it follows that he cannot prove Althen prong two. However, even if Petitioner had proven Althen prong one, the undersigned finds Petitioner has failed to show by preponderant evidence that there is a logical sequence of cause and effect showing Petitioner's flu vaccination caused his FM.

The primary reason that Petitioner has failed to prove prong two is that the onset of his symptoms did not occur until July 20, 2017. This onset date is inconsistent with a logical sequence of cause and effect, as discussed below. See infra Section V.C (discussing Althen prong three).

Next, the undersigned finds that while several of Petitioner's treating physicians opined that his FM was caused by vaccination, they did not provide the basis for their opinions, or they provided their opinions in non-contemporaneous affidavits.

On July 20, 2017, Dr. Thompson diagnosed Petitioner with FM, but he did not opine that the FM was caused by the flu vaccination. Dr. Thompson's contemporaneous medical records state no opinion as to causation.

On February 6, 2018, Dr. Kalb diagnosed Petitioner with MTHFR deficiency and FM. Dr. Kalb "assum[ed]" that the "flu shot in 2016 affected [Petitioner's] immune system and may have resulted in reactivation of EBV" which "may have led to the development of his . . . [FM]." Pet. Ex. F at 41-42. Dr. Kalb is the only physician who documented an opinion in his contemporaneous medical records. However, Dr. Kalb did not explain how the flu shot could have caused reactivation of Petitioner's EBV. Nor did he explain how a reactivation of EBV could cause FM. Dr. Kalb's opinions are stated as assumptions without explanation.

Treating physician statements are typically "favored" as treating physicians "are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). However, no treating physician's views bind the special master, per se; rather, their views are carefully considered and evaluated. § 13(b)(1); Snyder, 88 Fed. Cl. at 746 n.67. "As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019).

Although Dr. Thompson did not state any opinion about causation in Petitioner's medical records, he did later execute two affidavits that contain such opinions. In the first affidavit, signed in 2019, Dr. Thompson opined that Petitioner's "chronic symptoms represent an adverse reaction directly related to" his September 4, 2016 flu vaccine. Pet. Ex. 7 at 1. In the second affidavit, signed in 2020, Dr. Thompson opined that "no etiology has been found to explain [Petitioner's] persistent neurologic symptoms, other than the circumstantial evidence point to the fact his symptoms had their onset within days" of receipt of the flu vaccination. Pet. Ex. O at 1.

Several factors lead the undersigned to give Dr. Thompson's affidavit opinions less weight than what Petitioner might urge. First, Dr. Thompson did not offer these opinions in his contemporaneous medical records. And second, the only basis for his opinions appears to be Dr. Thompson's belief that Petitioner had symptoms "within days" of his vaccination. However, Dr. Thompson does not explain why he failed to note Petitioner's symptoms in his records when he saw Petitioner for an annual physical examination on June 13, 2017.

Third, Dr. Thompson's causality opinions only came into focus after Petitioner filed his petition, and the affidavits were prepared for the purpose of litigation. It is well-established in the Vaccine Program that contemporaneous medical records are given more weight than later-in-time statements to the contrary. See Burns, 3 F.3d at 417 (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"); Zumwalt, 2019 WL 1953739, at *19; Vergara, 2014 WL 2795491, at *4. The greater weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Cucuras, 993 F.2d at 1528; see also Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326; Ricci v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 385, 391 (2011) ("Medical records from years later, merely chronicling a timeline between vaccination and injury, are not worthy of the same consideration as contemporaneous records.").

A treating physician's opinion created for purposes of litigation may be afford less weight. See Gerami v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 299, 305-06 (2014) (finding the special master properly afforded petitioner's contemporaneous records more weight than a letter from a treating physician written for the purposes of litigation); Kaplan v. Sec'y of Health & Hum. Servs., No. 18-231V, 2022 WL 1873885, at *22 (Fed. Cl. Spec. Mstr. Apr. 28, 2022) (giving little weight to a letter written by a treating physician "requested after petitioner learned of the Vaccine Program and had been advised of attorneys in the Program"); L.M. ex rel. McClellan v. Sec'y of Health & Hum. Servs., No. 14-714V, 2019 WL 4072130, at *32 (Fed. Cl. Spec. Mstr. July 23, 2019) ("[I]t is reasonable to give a treater view reflected in the contemporaneous medical record (before thought of litigation has occurred) greater weight than a subsequent statement prepared specifically to support a Vaccine Act case.").

Here, Dr. Thompson's contemporaneous records do not contemplate vaccine causation. Because Dr. Thompson's affidavits in 2019 and 2020 are different than his earlier-in-time medical records, and because they were prepared for litigation, the undersigned finds the earlier records are more reliable.

The undersigned finds the 2020 letter by Dr. Gore, stating that he agreed with the letter by Dr. Thompson dated August 2, 2020, carries little to no probative value. Dr. Gore did not see or treat Petitioner until March 10, 2020, several years post-vaccination. Dr. Gore did not diagnose Petitioner with FM. Instead his assessment was chronic neuropathic symptoms of the hands and feet and chronic midline low back pain. Petitioner and his wife sent an email to Dr. Gore on January 30, 2021 asking why Petitioner did not have FM, confirming that Dr. Gore did not reach a diagnosis of FM. Therefore, it is not reasonable to conclude that Dr. Gore, by stating that he agreed with the letter of another physician, reached a diagnosis of FM, or offered an opinion that Petitioner's FM was caused by his flu vaccination. The undersigned affords the letter by Dr. Gore little probative value because it relies on the opinion of another physician, is inconsistent with Dr. Gore's own medical records, and it does not explain the reasoning behind the statements in the letter.

Lastly, Respondent's expert Dr. Jamieson opined that there were other causes for Petitioner's complaints, including degenerative spine disease, obesity, obstructive sleep apnea, folate deficiency, and low testosterone. The undersigned acknowledges that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation. See Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1149-52 (Fed. Cir. 2007) (finding a petitioner does not bear the burden of eliminating alternative independent potential causes). However, she finds it reasonable to consider "evidence of other possible sources of injury" to determine "whether prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." Stone, 676 F.3d at 1379; see also Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th 958, 963 (Fed. Cir. 2023) (finding that the special master's "contemplation of a potential causative agent when evaluating whether or not a petitioner has established a prima facie case is in accordance with the law").

Further, the fact that Petitioner sought treatment for kidney stones and hematuria, and his X-rays showed lower lumbar facet sclerosis and a left kidney stone on July 20, 2017, the same day that he presented to Dr. Thompson complaining of back pain, raises questions about the cause of his symptoms and "makes it difficult to attribute 'but for' causation to the vaccination." Pafford, 451 F.3d at 1358-59; see also Walther, 485 F.3d at 1151 n.4 ("Where multiple causes act in concert to cause the injury, proof that a particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine."). However, the undersigned does not find, nor does Respondent argue, that the evidence is sufficient to establish, more likely than not, that these other problems caused his FM.

For all these reasons, the undersigned finds that Petitioner failed to provide preponderant evidence of a logical sequence of cause and effect. Thus, Petitioner has failed to satisfy Althen prong two.

C. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; see also Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011). Thus, prong three contains two parts. First, Petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, they must demonstrate that the onset of the disease occurred in this period. Shapiro, 101 Fed. Cl. at 542-43.

Because Althen prong three coincides with Althen prong one, Petitioner's inability to meet his burden demonstrating how the flu vaccine can cause FM effectively precludes him from being able to meet his burden under the third Althen prong. Thus, because the undersigned

found that Petitioner did not offer a sound and reliable theory of causation, he cannot demonstrate that his condition arose in a medically acceptable timeframe pursuant to that theory. Even assuming that Petitioner satisfied Althen prong three, that alone would not satisfy Petitioner's overall burden of proof. Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury."). However, Petitioner's showing with respect to the third Althen prong is deficient.

Petitioner's expert Dr. Hagenau opined that the onset of Petitioner's symptoms occurred five to seven days after vaccination. He did not opine about whether this was an acceptable time frame given his opinion that FM is caused by a dysfunction in the central pain pathways. See Pet. Ex. R at 5. Dr. Akbari opined that FM is immune mediated and that both the innate and adaptive immune systems are involved in its pathogenesis. He offered several different causal hypotheses but did not specify the appropriate timeframe for onset applicable to each idea. However, regarding his causal hypothesis about the induction of inflammasome by innate immune cells, he opined onset would be "relatively fast" with the peak response between one to three days. Pet. Ex. DD at 26-27. Dr. Akbari generally opined that an onset of seven days was "textbook." Id. But he did not explain which specific hypotheses would fall within the seven day onset timeframe. And Dr. Jeret opined that onset of symptoms began a week or two after vaccination, which is consistent with his proposed theory of molecular mimicry and the onset of GBS after the flu vaccination. See Pet. Ex. BB at 13.

Respondent's expert Dr. Jamieson opined that the onset of Petitioner's symptoms was ten months after vaccination, in July 2017, and this onset was not within the time frame that would link it to his flu vaccination. Resp. Ex. E at 5. Dr. Staud opined that Petitioner reported that his onset of symptoms began three days after vaccination, which was "too long" for a nonspecific side effect of vaccination and "too short" for a specific immune system effect. Resp. Ex. D at 2, 5.

As set forth above, the undersigned finds that the onset of Petitioner's symptoms occurred July 20, 2017, when Dr. Thompson documented Petitioner had "pain all over his body" and fatigue and diagnosed Petitioner with FM. This places onset approximately ten months post-vaccination. As explained by Dr. Jamieson, this is far outside the window of vaccine-related causation for FM, and for any theory advanced herein by Petitioner's experts. Therefore, the undersigned agrees with Dr. Jamieson, that the onset was too long to be associated with Petitioner's flu vaccination administered September 4, 2016.

Accordingly, the undersigned finds Petitioner failed to provide preponderant evidence of Althen prong three.

VI. CONCLUSION

The undersigned extends her sympathy to Petitioner for his painful and chronic condition. The undersigned's Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that flu vaccine he received caused his FM. Therefore, Petitioner is not entitled to compensation and the petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master